State Pharmaceutical Assistance Transition Commission Meeting

Thursday, October 14, 2004

Sponsored by the

U.S. Department of Health and Human Services, Centers for Medicare and Medicaid Services
Baltimore, Maryland

Held at the
Holiday Inn on the Hill
Washington, DC

Audio Associates
(301) 577-5882

PARTICIPANTS

MEMBERS PRESENT:

Joan Henneberry, Chairperson
Clifford E. Barnes, Esq.
James Chase
Jay D. Currie, Pharm.D.
Janice O. Faiks
Dewey D. Garner, Ph.D.
Laurie Hines, J.D.
Mary Liveratti
Dr. Anne Marie Murphy
Julie A. Naglieri
Dennis O'Dell
Robert P. Power, M.B.A., C.E.B.S.
Susan C. Reinhard, R.N., Ph.D.
Sybil M. Richard, J.D., M.H.A., R.Ph.
Elizabeth J. Rohn-Nelson
Marc S. Ryan, M.P.A.
Linda J Schofield, B.S.N., M.P.H.
Martin Schuh, M.B.A.

CMS,HHS STAFF PRESENT:

Marge Watchorn
Deirdre Duzor
Katiuscia Potier
Suzanne Hassett

I N D E X

STATE PHARMACEUTICAL ASSISTANCE
TRANSITION COMMISSION

October 14, 2004

KEYNOTE: "---" Indicates inaudible in transcript.

M O R N I N G S E S S I O N

9:12 A.M.

CHAIRPERSON HENNEBERRY: Good morning. My name is Joan Henneberry and I have been honored to be the chairperson of the State Pharmaceutical Assistance Transition Commission since our first meeting in early July.

We have been working very hard since that time. And today is our, what I think will be our last open public meeting. And the main purpose of today's meeting is to present to interested parties who are here with us in the back to our preliminary recommendations.

And I will explain those a little bit more later about why they are preliminary and why you don't have them on paper. But I would like to start by letting the commission members introduce themselves.

Introduction of Commission Members and CMS Staff

by Joan F. Henneberry, Chairperson

CHAIRPERSON HENNEBERRY: And I think because we have such a small audience I am going to ask, and I think we have time to do this, so I am also going to ask each of you to stand and just tell us who you are and where you are from. But let's start down at the end with Marc and let you all know who is on the commission.

MR. RYAN: Good morning. My name is Marc Ryan. I am the State Budget Director of the State Office of Policy

and Management in Hartford, Connecticut.

MS. ROHN-NELSON: Good morning. I am Elizabeth Rohn-Nelson. And I am the public advocate.

MR. O'DELL: Good morning. I am Dennis O'Dell. I am Senior Vice President of Pharmacy Services for Walgreen.

DR. GARNER: Hello. I am Dewey Garner. I am Professor of Pharmacy Administration at the University of Mississippi.

MS. LIVERATTI: Good morning. I am Mary Liveratti. I am the Deputy Director for the Department of Human Resources in Carson City, Nevada.

MS. SCHOFIELD: I am Linda Schofield. I am an independent consultant from Connecticut.

DR. REINHARD: Welcome. I am Susan Reinhard, Deputy Commissioner of Health and Senior Services in New Jersey where we have the State Pharmaceutical program. Cathy Mason in the audience is the Director of that program.

MR. POWER: I am Bob Power from Health Partners, which is a non-profit small regional health plan in Minneapolis, St. Paul in Minnesota. And I am hearing impaired.

MR. CHASE: Hello. I am Jim Chase. I am Director of Health Care Purchasing with the Department of Human Services in Minnesota.

MS. WATCHORN: Good morning. My name is Marge

Watchorn. I am with the Centers for Medicare and Medicaid Services.

DR. MURPHY: Good morning. My name is Anne Marie Murphy. I am the Medicaid and SCHIP Director in Illinois.

MS. RICHARD: Good morning. My name is Sybil Richard. I am the Bureau Chief of Pharmacy Services with the Florida Agency for Health Care Administration.

MR. BARNES: Good morning. I am Clifford Barnes. And I am with Epstein Becker and Green, and am a partner.

MS. HINES: Hello. My name is Laurie Hines and I am here representing the SPAP in Missouri, Missouri Rx Program.

MS. NAGLIERI: Good morning. My name is Julie Naglieri. I am the Director of the New York State EPIC program which is the SPAP in New York.

MR. SCHUH: Marty Schuh, with ACS, External Affairs.

DR. CURRIE: I am Jay Currie. I am a faculty member at the University of Iowa, College of Pharmacy.

CHAIRPERSON HENNEBERRY: And if the people in back if you could just stand and tell us who you are and where you are from.

MR. DRESDEN: Good morning. I am Ryan Dresden, here with Health Strategies.

MS. WISEMAN: Debbie Wiseman from America's Health

Insurance Plans.

CHAIRPERSON HENNEBERRY: Anybody else back there? Okay. Thank you everyone. It's good for us to know who is in the audience. And I will explain the agenda and the format later so that all of you will know when you will have an opportunity to make comments.

I would like to start, because this is being recorded for the purpose of the official record of the commission, a couple of ground rules. Please, commission members, and I will remind you, we need to use microphones. But, also because it's being recorded and I want to go on record thanking a few people for their participation.

And we will be meeting as a commission a few more times. So it's not the last time we will talk to one another. But I do really do want to go on the official record of how hard some people, everyone has worked very hard. But in particular a few people.

And I would first like to thank Marge Watchorn, who was assigned to us by the CMS staff. I am not sure whose idea that was. And I don't know if she has lived to regret it. But she has done a yeoman's work for us.

(Applause.)

CHAIRPERSON HENNEBERRY: She has helped keep us organized and followed through and reminded us of things and done a lot of writing and editing for us. And she has a lot

more work to go. But, she has done a great job.

And I also want to thank Lethia Kelly, who you met outside who has done all of the logistics for the times that we have gotten together and has made it physically comfortable for us to be everywhere we needed to be so that we could do our work and focus on that.

I also especially want to thank all of my commission members. And there are a few missing who had to leave a little bit earlier who couldn't be at this particular meeting. But, everyone at this table has another real job. And they have been working very hard since the first of July.

Each subcommittee has been meeting every single week for at least an hour by phone. People have put in their own time doing the research and the background for the papers that they committed to do. They have been editing each other's work and reading each other's work. And they really have put in a tremendous amount of time on this.

And, again, we are not finished yet. But we are over the hump. And I really do want to thank all of you for your incredible work and contributions. There are --. I also as a former state person, I really do, with all due respect to my colleagues on the commission, those of us who are in the private sector or consultants, I do want to especially thank the state people.

I worked in state government and it's not an easy

place to be right now especially. They are all overworked. They are mostly underpaid. And in addition to the incredible responsibilities that they have as public servants every day they worked especially hard. And their contributions to our work on the commission were invaluable because the whole point of the commission was understanding how Part D was going to impact state programs and the beneficiaries that they are used to serving.

So I especially want to thank all of the state people. And I would like to thank especially Elizabeth Rohn-Nelson. Elizabeth is our consumer representative on the commission. And she kept us honest.

I mean every time we would be talking about things or we would get bogged down in some minutia and technical stuff she would raise her hand and say, “I don’t think consumers are going to understand that.” We said, okay. Well, we needed to know that. And we needed to talk about that then. And that was a very valuable contribution as well.

So again thank you all for your hard work. And hopefully we will be done on time. As you all know our report is due to the President and Congress the 1st of January. We are well on our way to that. And we will be moving after this meeting into the fine tuning, editing, refinement stage for our report. And you will hear about

that throughout the day as well.

I thought I would just, for those of you who were not here at our first public meeting in July, just remind the audience what the purpose and charge of the commission was. And it really, it was a recognition I think on the part of Congress that for the millions of seniors and disabled individuals in states who had been receiving services through state funded pharmacy assistance programs, there were going to be some very special issues around the transition that those individuals and the programs that serve them were going to face as we roll out the Part D benefit.

So that was really our mission from the very beginning. To look at the rules and regulations. To look at the program design and to think about how those, the design and the rules were going to affect the ability of state pharmaceutical assistance programs to continue to operate. What role they could play. How they could coordinate benefits. How they could make the transition for the beneficiaries they had been serving as easy as possible.

And that word “easy” actually has been used. And you will see that in our principles. So all of the work that we did, the deliberations, the research we looked at, the guest speakers that we had present to us, we tried, and I think were successful in keeping our heads always in the mode of how does this affect the state pharmaceutical assistance

programs' ability to stay in business and to keep doing good work for the people that they have been serving. Some for 20 years or more.

So that is what we were charged with. And we began our work in July at the first public meeting where we heard testimony and heard reports and information from people, like Kim Fox, who has been doing research and following state programs for quite some time.

We heard from the state programs themselves. We began to set up a schedule and meetings. We broke into subcommittees. We have had, as I said, guest speakers and thought about other individual we needed to have to better inform our decisions and our recommendations.

But every time we thought about making a recommendation or modifying a recommendation we asked, it had to go through the test of what does this have to do with the state pharmaceutical assistant program or their beneficiary. And that is how we tried to do our business and stick to those rules.

We organized ourselves, as I said, around subcommittees. As we began to hear the testimony and meet the first time in July, we said we can't, 23 of us can't just constantly sit at a table and try to hammer everything out. We have to break into some smaller groups.

So we ended up with three work groups. One that

focused mostly on beneficiaries. Although there was overlap often times between these three groups.

But the first group really tried to focus on all of the things that a consumer would be most concerned about. And all of the parts of a program design and how you read the design in an SPAP program that would affect, directly affect a consumer and the needs that they would have to understand how this program is changing.

The second group focused mostly on actual program design and what would an SPAP look like in the years to come as it tried to evolve and develop and be as good of a program as it could be and coordinate benefits and that sort of thing.

And then the third group focused on what we called systems infrastructure. We used a variety of names for this. But they really, they got into some very deep but important detail around how information has to be exchanged. How do you actually put systems together. What needs to be in place to make this work. What do you do about all of the challenges around the differences between what the PDP sponsor plans and the SPAP might look like.

So, you will see when we go through our recommendations they don't always flow in that order. Because, as I said, there are, there definitely were some overlapping issues between those three groups. But you will

see the recommendations for the most part roll out in that order.

We made decisions by consensus. Things bubbled up from the subcommittees. As I said they were meeting almost, well pretty much every week since July by phone and then doing research and work on their own.

So the committees, each committee would have discussion around a recommendation or a draft of someone's paper. They would continue to work on that and refine it until they felt it was ready to present to the rest of the commission. To the people on the other committees.

The other committee members would read things. And they would also look to those papers to make sure that one subcommittee wasn't recommending something that was in conflict with what another committee was recommending.

So during the times that we met in person as a group that was the focus of our discussion. To look at the crosscutting issues between each of the groups and to build consensus up from the work that individuals did, then committees did, and then what you are going to see in a few minutes are the recommendations of the entire commission that were built on consensus.

And you will see at the end as well we have a few unresolved issues. Things that we are still discussing. We are not quite sure where we are yet. And you will see those

at the end.

Overview of the Charge and Responsibilities of the Commission. Review Agenda and Ground Rules for Comments

by Joan Henneberry, Chairperson

CHAIRPERSON HENNEBERRY: So let me just tell you a little bit about our ground rules for the day and how we are going to do this.

We have about 30 slides that we are going to show you. And we very deliberately did not give you handouts on this because these are preliminary. We are counting on you to give us reaction and response and input to the recommendations.

And the committees will then take the input that you give us and go back and revisit their recommendations. And see how, if at all, they want to incorporate that feedback or modify their recommendations.

So these are preliminary. We want your input so that we can then make changes before our publication and our report and recommendations become public in writing.

We do ask that you come up to the microphone. And I will explain the process in a minute. And we will have a couple of breaks today. So, we have no idea how long this will take. We rehearsed yesterday. We could, if you weren't here, we would go through these pretty quickly. But, we have

left the entire day expecting and hoping that there will be some audience response and comments to most of our slides.

So what is going to happen here is I am going to, Marge is going to flip the slides for us. And for each slide one of the commission members will explain it and give you some background on why we are making that recommendation. And then you will have, and I will ask you if anyone wants to respond to that or give us additional comment. And you will be invited to come up to the microphone and do so.

And we will take notes and, as I said, then as a group we will come back and look at those comments again and think about them and see where they belong.

I will periodically, after the breaks, in case you think about something a little bit longer and want to come back to an earlier slide, I will check back with you also during the breaks.

The commission members will always, are always welcome to add additional comments as well on any of the slides, even if it's not one that they are responsible for speaking to.

Okay. Any questions about process? Is everybody clear on --? You will see how this goes. We did this yesterday. So, it actually worked pretty well. So.

(No response.)

CHAIRPERSON HENNEBERRY: All right. I am going to

start by sharing with you some overarching principles that emerged throughout our deliberations and discussions. And some of these emerged very quickly.

If you had been here at our first meeting in July, the public meeting, and heard some of the early discussion, some of these are not going to come as a big surprise to you.

But there were a number of things that drove our work that we felt very clearly and strongly about either from the beginning or as our work evolved. And again these were things that we tried to follow as a test and things that were important to us as we got into additional recommendations or sub-recommendations.

The first is that we, all of the work we have done is based on an assumption that we want to make sure that current SPAP members have uninterrupted access to medications. That is the number one thing that was important to us. That, again, the people who have been served in current SPAP programs, and you will hear more about this.

We know there is going to be confusion. It's going to take time to coordinate things. But this is really the ultimate goal here. That people don't go without the needs they need in terms of their medications.

We wanted, because of our mission, again, the whole point of the commission is to think about how SPAPs can change and evolve and do what they need to do to coordinate

benefits. We wanted our recommendations to create a framework that would make it easy for SPAPs to coordinate with PDP sponsors, the prescription drug plan sponsors.

Again, that was a very important principle and value that we tried to follow. So when we talked about specific recommendations we said, well, is that going to make it harder, easier. It might sound on the surface like it would work just fine and then as we get to layers of detail we say well wait a minute that is just going to cause another set of problems over here.

So we tried to make sure that our recommendations helped to create and support that framework. And imbedded in that was the desire to encourage state flexibility and choice. And not to take away any of the flexibility that states already have to make those programs serve their enrollees in the best way possible.

And we also wanted to make sure we constantly checked and made sure that whatever we were recommending wasn't going to shift more cost to state pharmacy assistance programs that already exist. We wanted to minimize that.

We believed very strongly in the seamless coordination of benefits. Coordinating benefits in the healthcare system under any circumstances for any person is not an easy task. But there are things that can make it better and easier. And you will see a number of

recommendations we are making to do that.

We believe very strongly in realtime information exchange. That the more information that everybody involved in the care of an individual, especially an elder person, a disabled person, somebody with many chronic illnesses, the more information that everybody can have at any given point in time in realtime the better the care for that person will be. And we felt very strongly about that.

(Slide)

We believe in minimizing paperwork and maximizing the use of technology. And we heard some exciting and interesting presentations from experts who helped us understand the technological possibilities better than most of us came to the table understanding them. And that was actually kind of fun and we learned all sorts of interesting things about that.

We also felt very strongly, although it was not our mission to discuss or deal with the discount cards, or that particular temporary program or to evaluate it. There were some very, very important lessons that especially the state pharmaceutical assistant programs learned from the roll out of the discount cards.

So we wanted to apply all of the positive and needs improvement lessons that came from the roll out of that program to make sure that we didn't make the same mistakes

with the roll out of Part D and that we built on whatever was successful from the roll out of the discount cards.

And finally we spent a lot of time talking about education and marketing. And we acknowledged throughout the enormous challenge that all of us will be undertaking, CMS, advocacy organizations, consumers, consumer groups, states, local entities.

The amount of work and the challenges to informing the public about the benefit and helping them understand the benefit and helping them understand if they are in a state that has a state pharmaceutical assistance program how those things work together.

This is going to take a lot of work. And it's not going to be easy and we acknowledge that and we acknowledge how much we are all going to have to work together to make it be successful.

(Slide)

So that is where we started. And what I would like to do now is to just start moving into some of the specific recommendations. Individual commission members, as I said, will present these to you. They are broken up as I mentioned earlier pretty much fall into the categories of eligibility and enrollment then drug coverage and service delivery and then coordination of benefits.

Before we start do commission members or anyone in

the audience, do you have any comments or reactions to our general guiding principles? Anybody want to say anything else about that?

(No response.)

CHAIRPERSON HENNEBERRY: Okay. Oh, Marc, go ahead.

MR. RYAN: I think on behalf of the commission you thanked a lot of people. And we just want to thank you for everything you have done. It's absolutely amazing to think that this commission could accomplish everything without all the coordination you have done.

You have been a great task master and a great facilitator. And you have such wonderful knowledge about all of these issues. And, again, we just want to thank you for all your work as well.

CHAIRPERSON HENNEBERRY: Thanks Marc.

(Applause.)

CHAIRPERSON HENNEBERRY: My pleasure. And when I start pounding on glasses you know I am really --. All right. Thanks.

Preliminary Recommendations from the Commission.

Public Comment and Questions

by Joan F. Henneberry, Chairperson

CHAIRPERSON HENNEBERRY: Okay. I think, all right, we are ready to turn to eligibility and enrollment. And Susan Reinhard chaired this workgroup. And I think you are

up on slide number one.

Work Group One - Beneficiary Transition

Eligibility Determinations

by Susan C. Reinhard, R.N., Ph.D.

DR. REINHARD: Okay. Well first I would like to thank the members work group one. We have Anne Marie. Everyone knows last names. So, Cliff, and we have Elizabeth, and Mary and Jan, we hope is joining us.

And most of us will say a few words about some of these recommendations that we have. But we wanted, before I just go to the recommendations by way of background I think that Joan's presentation of the principles is incredibly important because it really did drive our thinking about where it begins with eligibility determinations.

And that if you think about the current way that we expect beneficiaries to get into this program it is a very complicated two step process. And I know that this is a very sophisticated audience, but just to put it on the record this is a very complicated two step process.

And if we don't make this as easy as possible for seniors and people with disabilities for Medicare beneficiaries we are likely to fail in making this work smoothly.

So we really took that principle of trying to make this as easy as possible both for seniors and for the states,

that the state pharmaceutical assistance programs hereon after known as SPAPs to see if we could try to simplify this, make it as efficient as possible.

And although I know that Medicare, we know that Medicare is considered a national program and that we need national standards, the reality of this is this is very much a state federal partnership if our goal is to wrap around benefits and to offer the most, the fullest benefit coverage we can possibly offer to people on Medicare.

So we think that state flexibility is crucial here to make this as easy as possible. Some states are prepared to offer this kind of one-stop shopping. Other states may not be. So we understand that we do have to have choices for states. One of our principles.

Many of these programs, as Joan has indicated, have existed for decades. New Jersey is going to be celebrating 30/35 years before you know it. And the same would be true for some other states.

This is a trusted source for seniors. In fact it's hard for us to imagine that they would go any other place than to their state pharmaceutical assistant program.

So these two recommendations flow from that discussion that we have had. And we unanimously agreed that both federal agencies, both the Centers for Medicare and Medicaid Services, known as CMS, and the Social Security

Administration, known as SSA, should make it very clear, should explicitly state that SPAPs can do this job. That they can, if the state wants them to, that they can continue their historic role in trying to enroll, to determine eligibility for these Medicare beneficiaries.

We know that some states, Illinois, New Jersey are two of them, have been doing eligibility determinations through memoranda of agreement with their state Medicaid agencies. They have been doing that quite successfully. So this is not something new for those states that may choose to do this.

So we considered this an option. And the second part of this would be an addition that it's crucial that SSA should allow the coordination of eligibility determination and re-determination, which means that annual renewal, that annual application that beneficiaries are going to need to do.

And that could be done in a number of ways. At minimum through sharing electronically data. If the state pharmaceutical assistance programs are willing to collect information on the very forms that SSA has determined are required that we can do that for our beneficiaries and transmit it electronically. That would be one example of coordination.

So that both the SPAP and SSA have the information

that we need to determine who is eligible for both the SPAP and the Medicare benefit. We have to remember these are two eligibility processes. How we join that together.

Ideally, we would love to see SSA contract with SPAPs to do this work to make it more efficient, more senior friendly. But, again, the goal is at least coordination and simplification. So those are our two recommendations.

CHAIRPERSON HENNEBERRY: Okay. Thank you. Can you all hear in the back? Are the mics good enough for you?

(Nodding of heads.)

CHAIRPERSON HENNEBERRY: All right. So I invite any comments, reactions, support, disagreement from anyone in the audience. And if you would like to comment just go up to the microphone and tell us your name and share your thoughts with us. If not, we are just going to keep moving through the slides.

But again I will check with you, hi, Kimberly. I will check with you at break times in case you think of something later on and want to come back to it. Good morning.

MS. FOX: Always the outspoken one. Kim Fox from Rutgers. I think these are great recommendations. The two things that I would add potentially in the spirit of sort of learning from the discount card is in the event that states don't get some of the other things that you may be

considering, such as auto-enrollment, one of the key issues that the education of beneficiaries in the discount card was that CMS' education materials didn't actually explicitly mention the state pharmacy assistance programs.

And we actually asked them about it it was sort of too late in the game at that point to incorporate even --. They had said they couldn't do state specific letters. But they could have at least had some general reference to oh, if you have a state pharmacy assistance program in your state you may want to contact them first.

And I am just raising this because it really could be also beneficial in the case of the SSA letters that go out that that kind of very specific information is included and that we don't go through the same mistake that we went through with the discount cards. That is one comment.

And my other comment is just a question as to, I mean since we know that this two stage application process is going to be extremely cumbersome, again in the case of the discount card there wasn't two stages. And so I am wondering why the commission didn't comment on basically eliminating one of those stages.

CHAIRPERSON HENNEBERRY: Does anyone on the commission want to respond to that?

DR. REINHARD: I think that is a great idea. Maybe think we should take it up in our discussion after this.

Thank you.

CHAIRPERSON HENNEBERRY: You will see some slides later about auto enrollment. And you will see a slide on marketing materials and printed information and that sort of thing too.

DR. REINHARD: But I do, just for Kim's, because we were nodding here, well we do have a slide on marketing principles. But I think what Kim is suggesting is different than what we have and should be taken note. And that is that the letters that SSA is going to send out, not just the pharmacy programs, but SSA, that they should be tailored to the state. And I think that is a very important recommendation coming from the audience.

CHAIRPERSON HENNEBERRY: Okay. Any other comments from commission members or the audience on this slide?

(No response.)

CHAIRPERSON HENNEBERRY: Okay. Let's go to the next slide. And I think Anne Marie you are taking this one on asset determinations.

Asset Determinations

by Dr. Anne Marie Murphy,

DR. MURPHY: Right. This recommendation comes out of our desire at the commission to make this program as accessible as possible for beneficiaries and also as easy to administer as possible.

States have a lot of experience in this area. And in fact states themselves when they have been designing pharmacy programs have in general chosen not to have asset tests. And the reasons are many.

In particular many when you actually survey seniors, many do not actually have assets and so the costs of administering an asset is actually larger than the amount you save. And denying people access to the program based on the low income subsidy based on their having assets.

And so while we know that the law includes the asset test we suggest that Congress revisit that issue and eliminate the asset test. Many states in the last two years in their children's health programs have done away with asset tests and they have done that for a good reason because they found it ineffective and a larger barrier to many eligible people enrolling.

In the absence or until Congress does revisit that particular issue we have a variety of recommendations. Firstly, given that we know that in general many will be applying at the same location that they apply for the Medicare savings program and in fact the law does require that and those that are accepting these applications in the state actually facilitate enrollment in the Medicare savings program.

We believe that states should be given the

flexibility to use the same asset rules that they use in the Medicare savings program.

Additionally states have a lot of experience in dealing with life insurance policies and I think that most will tell you that it's an extremely complicated area. And therefore we suggest that CMS clarify their proposed rules to eliminate life insurance policies as counting towards assets.

Finally, we also believe that vehicles should not be counted as assets. Many beneficiaries rely on their vehicles to get to their medical care and to other very important life functions. And therefore many states themselves in fact discount vehicles knowing of this. And we feel therefore that vehicles should not be counted as assets.

The last issue that we believe is important is that CMS should really take another look and determine the applicability of an asset test based on cost benefit analysis.

I think that some serious and statistical work looking at the costs of administering an asset test versus the purported savings in regards to keeping some individuals from accessing this particular benefit need to be addressed so that we can make informed choices as to whether it really makes sense to have an asset test.

CHAIRPERSON HENNEBERRY: Okay. Any questions or response from the audience?

(No response.)

CHAIRPERSON HENNEBERRY: Commission members? Anybody want to add anything?

DR. REINHARD: We just want to clarify about the vehicles. That we had a lot of discussion at one of our meetings and CMS did note that in the preamble there is a discussion about vehicles.

But we want it clearer in the regulations because when state administrators need to do their work they look very carefully at the actual regulations. So we think this is the spirit of what CMS was thinking. But we need it clearer.

CHAIRPERSON HENNEBERRY: Okay. No questions about this one?

(No response.)

CHAIRPERSON HENNEBERRY: All right. Mary. Marketing materials.

Marketing Materials

by Mary Liveratti,

MS. LIVERATTI: I would also like to thank Kim Fox for her comments. And as Joan has already mentioned, although I am dealing with marketing I think those comments also pertain to beneficiary education which will be covered in later slides.

But when we were looking at this issue in the work

group and then as a commission one of our concerns has been the confusion that seniors and folks with disabilities have experienced in trying to understand the drug discount card.

So we want to make sure that the system for Medicare Part D is simplified. That states are working together with their PDPs that are in their regions. And the PDPs are working with the states. Because the bottom line is we need to make this as simple as we can. As clear, so people can make choices and informed choices.

So we are very concerned that confusion be kept to a minimum. We feel that the marketing materials that are sent by PDPs should include information about the SPAPs in their regions, the State Pharmacy Assistance Programs. I think I have a hard time saying SPAPs, but maybe I can.

But the confusion is going to be even greater than with the discount cards because we will be having information about premiums. We will have information about deductibles. We will have information about the coverage gaps in the benefit. And SPAPs are willing to fill some of those gaps.

So it’s very important that people are informed of that because with the confusion over all those decisions and information they will be receiving, we are concerned that that may, some people may be more disinclined to try to enroll in Part D benefits. And SPAPs are there to provide some assistance for folks making those decisions.

We also recommend that the marketing materials should also be in other languages as appropriate to the region that they are serving so that we can reach some of those hard to reach populations.

CHAIRPERSON HENNEBERRY: Okay. Any questions or comments from anyone in the audience or other commission members?

(No response.)

CHAIRPERSON HENNEBERRY: Okay. It's pretty straight forward. All right. Susan, Auto Enrollment.

Automatic Enrollment

by Susan C. Reinhard, R.N., Ph.D.

DR. REINHARD: Yes. We have been speaking about this two step process. I have already addressed the eligibility determination component of this. This automatic enrollment has been the topic of concern for us from the beginning.

Principles here that we held in our minds were expanding beneficiary drug coverage. That is a very central goal in relation to automatic enrollment. Facilitating coverage through the SPAPs. And again making it as easy as possible for beneficiaries.

It is complicated. We do have lessons learned from the Medicare drug discount card. The feedback has been extremely favorable from beneficiaries in my state as well as

others.

CMS has been extremely helpful in that regard. And we do have provisions regarding opt-out that is available. But we found few beneficiaries really did choose to opt-out because it was easier for them.

The regulations do provide for enrollment through a PDP or other enrollment process permitted by CMS. So the SPAPs believe that they can serve as this alternate enrollment process that CMS could approve. And we will say other comments about that.

The three recommendations on this slide are that SPAPS should be considered authorized representatives on behalf of beneficiaries for purpose of applying for assistance, and enrolling in plans.

That SPAPs should be permitted to select one or more preferred plans with an opt-out provision. And we are going to address both the preferred plan and the opt-out provisions. Two other commission members will address that as well.

And that SPAPs should be allowed to enroll members into one or more preferred plans and pay premiums on behalf of their beneficiaries. We will speak again in another slide about paying premiums. But those are three basic recommendations.

CHAIRPERSON HENNEBERRY: Okay. Again for those of

you in the audience who joined us after I gave the format instructions, if you have comments or reactions to our recommendations you are welcome to come up to the microphone and share those with us. And other commission members can also comment and add. Hello, Kathy.

MS. MASON: Hi. Kathy Mason from the New Jersey SPAP. And I just wanted to respond to Kim Fox's earlier question about a two step process. To say that if the states were allowed to determine eligibility and then automatically enroll at a preferred sponsor, the two step process would be combined into one in that the beneficiary would just be working with the SPAP for both eligibility and enrollment. And that would address Kim's concern about the two step process. Thank you.

CHAIRPERSON HENNEBERRY: Thank you. Any other questions or comments from the audience or other commission members on the auto enrollment recommendations? Bob.

MR. POWER: I represent a health plan in Minnesota. And one might think that we would be concerned about this central recommendation of an ability for SPAPs to declare a preferred PDP with which they would like to work.

On the contrary. I think that the drug discount card showed us that the depth of confusion was so great for a discount card and Part D is going to be so much more complex that on balance I think it's smart for an SPAP to be able to

declare a preferred PDP even through that might sound like it's sending people to our competitors.

In fact I have been reassured by the attitude of my fellow commissioners of their willingness to acknowledge the need to coexist peacefully with health plans, private health plans including the ones that exist now and the ones that will come into being in the context of the MMA.

So I think here a reduction in confusion trumps the competitive aspect that might otherwise reign about this topic.

CHAIRPERSON HENNEBERRY: Marc.

MR. RYAN: I certainly appreciate Bob's comments. As the representative of the one state that actually wrapped around for the discount card all 15 cards in our state.

I can tell you we thought it was going to be easier than it was. We are having a number of implementation problems just because of the sheer magnitude of coordinating with multiple vendors out there. And getting data between federal government, state government, and now the card providers.

Up until a few weeks ago we had about half of our recipients without drug discount cards as of yet. And that is not a big issue for them because they are enrolled in CONNPACE and we have the ability to draw down on the low income subsidy in the future.

So they don't lose out. And hopefully we don't lose out. But I do fear if you are going to have to engage in that kind of wrap around as Bob points out that would essentially, I believe, compromise access to prescriptions along the way, be it as mistakes, and it certainly would hurt the system, I think.

So I appreciate that the private sector understands some of the state issues surrounding here. And I really hope that if CMS does not want to allow an SPAP to endorse one card, at least we make it down the road to where we can have at least a number of preferred cards or at least limit the amount of wrap around a state may have to do ultimately and not have to wrap around any willing PDP in a state for example.

CHAIRPERSON HENNEBERRY: Okay. Any audience comments?

(No response.)

CHAIRPERSON HENNEBERRY: All right. Our next slide is endorsement of preferred plans. Susan.

Endorsement of Preferred Plan(s)

by Susan Reinhard, R.N., Ph.D.,

DR. REINHARD: The comments just made by my colleagues certainly speak to this as well. It flows from our previous slide that CMS should permit SPAPs to endorse one or more preferred plans to a variety of mechanisms.

The State of New Jersey and others used request for proposal technique. Where we could write in the criteria to simplify the choices to get the best value to work with a partner who would understand how to work with older adults, et cetera. The best plan that we could get.

Other states, as Marc has indicated, took a different approach. So again we do think that states should have the options of how they want to do this. But in general endorsing preferred plan simplifies choices for the SPAP beneficiary. We want the best plan as they do. That has allowed us to obtain the best value and encourage continued participation on the part of SPAPs.

As Marc indicated the more complicated this gets the more likely a state might just throw up its hands and say we just can't deal with this. We are just going to have to give up our program, depending on how *big? and historic* [I don't understand the part in italics…] the program has been.

Improving coordination of benefits, known as COB, coordination of benefits, and that helps relieve the need to regulate coordination of benefits. The more we can do this in a collaborative way the easier it is for all parties involved.

CHAIRPERSON HENNEBERRY: Any questions or reactions to the notion that a state program could select a preferred plan for their enrollees in Part D?

MR. SCHUH: Joan, I have one comment or a few comments on that.

CHAIRPERSON HENNEBERRY: All right.

MR. SCHUH: I represent a company that is --.

CHAIRPERSON HENNEBERRY: Could you move the mike just a little closer.

MR. SCHUH: For a company who is considering becoming a part of the PDP/MA-PD's base, this is essential. Because as we saw again the discount card, that unless you have the enticement of block enrollment, that is to say a couple of thousand enrollees at a time, it's quite a challenge to get the enrollees to sign up electively for a card.

So as a private sector enterprise it's key that we could offer the states something in exchange for that block enrollment. And that option if you take away the preferred PDP is going to be a challenge to overcome.

CHAIRPERSON HENNEBERRY: Any questions or comments on this?

MR. RYAN: Joan.

CHAIRPERSON HENNEBERRY: Yes. Marc.

MR. RYAN: Not to belabor the point but in our state we have, and it's been fairly limited I admit right now, but we do have anecdotal evidence that because of the confusion on the part of the providers, state government,

federal government, pharmacists, and even the plans in some cases, we have actually had individuals denied drugs at the pharmacy because they did not yet have a card.

For example, from the drug discount card vendor. They did have a CONNPACE card, but the pharmacist said well your first draw down is on the drug discount card. I am not going to give you your drugs.

And that, you know, I think people have to realize we are dealing with those real life implications. So if we can't limit the number of PDPs I think the chances that we are going to see even more of these type of things will increase dramatically especially with a much more complex environment.

So, there is the real life consequences here that I think can and will occur if we aren't able to master wrapping around or dealing with the more limited universe of providers in SPAPs.

MR. SCHUH: That is a good point because not only does it save the beneficiary hassle and the pharmacist hassle but it also provides the state with a less administrative burden to wrap around 12 plans as opposed to five plans must be exponentially harder with the data fees and the COB and everything else.

So I think it's entirely feasible that CMS could give guidance to us of the SPAPs to limit the number of wrap

around plans and options to make everyone's lives a little less complicated.

MR. CHASE: And Joan, unlike Marc, I will belabor this point because I do think it's one of our most important, one of our very important recommendations here that I don't think is totally uncontroversial. So we think it's important to underline this.

The other issue around coordination of benefits as you point out it would simplify it for the states, but I think also from the regulatory point of view of regulations COB, every state SPAP may have differences.

One of the things we recognized is there is a lot of variation. So if you don't allow states to make some choices here you are almost forced to make sure all the PDPs can meet the needs of all SPAPs in their area. And that could become very burdensome on the PDPs as well.

So this may be sort of a mutually beneficial approach if we can just allow some differentiation for plans that best meet the needs of SPAP recipients.

CHAIRPERSON HENNEBERRY: Okay. Any questions about that? Everybody in the audience who completely understands what we are recommending raise your hand.

(Show of hands.)

CHAIRPERSON HENNEBERRY: Okay. All right. Let's move on then to non-discrimination. And I think, Cliff, you

are going to take this one.

Non-Discrimination

by Clifford E. Barnes, Esq.

MR. BARNES: This slide deals with the non-discrimination provision. I think what makes the possibility of the preferred plan to coexist with the definition of SPAPs, which by definition is an entity that is providing financial assistance that is not discriminating based on the Part D plan is this non-discrimination provision, which provides that there should be an opt-out provision to protect the beneficiaries' free choice.

So, even though they may be auto so to speak enrolled in a plan they have the option to opt-out into any other plan that they so choose. The non-discrimination provision, it says, in the statute therefore should be satisfied. And we think it is. Even though it is contrary you might say to what is provided in the preamble.

The preamble we think goes a bit further then what the statute and the regulations provide. And, therefore, we think that the opt-out provision does satisfy the non-discrimination requirement in that definition.

In this way we protect the enrollees' ability to choose. We also provide the same benefit, at least the actuarially equivalent benefit to that individual in the plan that they so choose.

And in effect it is the same process that the federal government is using with the dual eligibles. Indeed with the dual eligibles their order was signed in an order enrolling them and they have an option to opt-out.

And indeed we are saying that the SPAPs should in effect have that same ability to, and thereby meet their non-discrimination requirement.

CHAIRPERSON HENNEBERRY: Any other comments from commission members or questions, reaction from the audience?

(No response.)

CHAIRPERSON HENNEBERRY: Okay. Moving to low income subsidy. Bob.

Low-Income Subsidy

by Robert P. Power, M.B.A., C.E.B.S.

MR. POWER: Okay. Now we switch gears to a relatively complex technical issue. Sorry about that. I will try to make this as clear as I can.

As prefaced, it's clear that SPAP members are not typical Medicare members. They do not have, typically do not have average type characteristics. And because the main payment to a PDP sponsor, whether it's a PDP or an MA-PD, such as my company, because that payment is capitated and it transfers risks it needs to be, it's critical that that payment stream is risk adjusted.

Risk adjustment is used to recognize some needs for

extra payment but all needs for extra payment for SPAP members. There are three ways in which these differences appear.

The first is differences in morbidity. The second is in enhanced benefits. And we will talk about that in a minute. And then the third one is what is called induced demand and different words than that are used in the preface of the NPRM, the Notice of Proposed Rule Making. But nevertheless this idea is in the NPRM.

We know that the first two concerns are going to be addressed by CMS' current plans as to how it's going to operate the risk adjustment system. That is the differences in morbidity between SPAP members and typical Medicare members will be addressed through the risk adjustment aspect of the payment.

The second one, enhanced benefits, will simply be reflected through the way in which payments are made. There are quite a large number of groups of low income beneficiaries that are characterized by the preface of the NPRM. They are called groups, group one, two, three. So that most people would be in the standard benefit.

And then other people will have their benefit improved. For example, from a $250 deductible up to a $50 deductible. And that is called group one. And I won't try to get into the technicalities of the other groups.

But the point is that their benefits are richer and health plans and PDPs are simply going to be paid more for those members than they would for somebody with a standard benefit.

The third one is the problematic one. And that is induced demand. Induced demand occurs because they have better benefits. Not because of the benefit itself. But rather because any hesitancy to get the drug will be reduced by the better benefits.

We would suggest the use of a special separate payment factor for induced demand. And then to go on to the last bullet on this recommendation page we are going to suggest a short-term incentive that would be paid to a PDP that enrolls a low income person as opposed to one who enrolls a middle class Medicare beneficiary.

We would have this disappear over time. But the point would be to make the low income people slightly more attractive in the short term than a standard benefit.

Unfortunately it's likely that this provision will have to be benefit, excuse me, budget neutral, which means that the additional payments made for low income people would have to be taken out in some fashion from the other recipients.

So I hope I haven't bludgeoned you with these complex ideas. I certainly am going to answer questions.

CHAIRPERSON HENNEBERRY: Okay. Any questions from the audience? Do you need any clarification on that?

(No response.)

CHAIRPERSON HENNEBERRY: And commission members. Linda did you want to add something?

MS. SCHOFIELD: I would just add that one of our concerns is that we want to make sure that companies, private sector companies who really have had no experience in many cases with dealing with this population.

And where there is a dearth of data on likely utilization patterns for Medicare drug benefits in general as well as some of these low income subsidized populations, some of whom have never had benefits before.

That these create a natural and understandable disinclination on the part of private sector companies to move into this space. And we were concerned that companies that have the highest premiums in fact would not have to take any of these people because the federal rules for auto enrolling folks state that they would only auto enroll duals for example into plans. And they would only provide low income subsidies up to the level of the average premium.

So if you have a private sector company that can avoid this population that might be a little bit scary to them in the first place by having the highest premiums that makes it a bit too attractive to avoid this population

entirely.

So that is why we felt it was important to have an actual incentive for companies to move into this space and get some experience with it at least for the short term.

CHAIRPERSON HENNEBERRY: Any other comments from the commission or the audience? Question?

(No response.)

CHAIRPERSON HENNEBERRY: A couple of commission members have mentioned the NPRM, the Notice of Proposed Rule Making. And I will just mention the commission did submit our own comments on the rules. And many of the recommendations you are hearing today can also be found in our comments on the proposed rules.

And I believe those will be, CMS is working its way through what I suspect is a room this size filled with paper. And I believe those will be public. So, you will have access to those at some point when they are all catalogued and put online or whatever they are doing.

Okay. We are going to move on and try and get through the next couple of slides. Then we will take a little break. So, premium payments. Mary, I think you are up here.

by Mary Liveratti

MS. LIVERATTI: Some SPAPs have expressed interest in paying the premium costs on behalf of the beneficiaries. If the SPAPs are going to pay that premium, they do not want their beneficiaries to have to pay for it first and then be reimbursed for those costs later.

Our recommendation is that if SPAP has paid the premiums they would like to do it up front on behalf of their beneficiaries so they can be sure that beneficiaries will maintain their Medicare Part D coverage.

Also, with the three levels of premium groups there is concern that especially for the group that is 135 to 150 percent of the federal poverty level they will be on a sliding scale premium, which means that everybody in that group could possibly have a different premium cost which again adds to the complication and makes it more difficult for SPAPs to coordinate with that.

So we are recommending there has to be a coordinated effort between CMS and the SPAPs to make these payments which we feel would be easier if we were able to pay for those up front.

And then our second recommendation is that we recommend there be an automated buy-in system in place by January 1, 2006, so that that could occur up front. And it would be similar to how states now have experience dealing

with paying for the Medicare Part B premiums. So it would be along those lines, but would save the beneficiaries from having to incur those costs first.

CHAIRPERSON HENNEBERRY: Okay. Any questions? Response, or additional comments from commission members? Marc.

MR. RYAN: I think that that was an amazing point. If you don't allow the states to pay it up front not only is there that expense to the individual potentially but also it creates administrative issues with states who would even like to credit it.

It would force us to look at crediting them by not having enrollment fees which create administrative burdens for us for those who may or may not be enrolled. It creates issues of if you were going to defer co-pays and things of that nature.

So I think would really be clean very much up front and it can be very easy for federal government and states given the QMB and SLMB type of programs we have out there.

CHAIRPERSON HENNEBERRY: Anything else?

(No response.)

CHAIRPERSON HENNEBERRY: Okay. And Susan. Late enrollment penalties.

by Susan C. Reinhard, R.N., Ph.D.

DR. REINHARD: In this same vein there are some SPAPs, State Pharmaceutical Assistance Programs that intend to not only pay the premium but even deal with the late penalties.

The way this works now as we understand the proposed regs is that there will be a one percent per month penalty for beneficiaries that do not sign up as soon as they are eligible, age 65, et cetera, which will mean that this problem grows every year and down the road could be a huge penalty for those that are not signing up right away.

For those State Pharmaceutical Assistance Programs that plan on paying that on behalf of their beneficiaries and that may indeed not be all states, but for those states that do, we would like to, the commission is recommending the same consideration for the full subsidy duals.

That will be only charge 20 percent of the late fee for the first 60 months. So SPAPs are seeking the same consideration for their beneficiaries.

We do have a lot of questions. This was something that came up relatively later in our discussions. We are not really clear even for the duals who is paying for the duals and what happens to that money.

We understand CMS does not plan on doing anything with those late penalty fees for quite some time. So we are

not really sure why states would be paying CMS late penalty fees when there isn't really a plan for what is happening.

So I think we need more discussion and understanding what the idea is. I think we do understand that the concept of a late penalty fee is to avoid having a situation where people sign up late only because that is when they need it most. That you would have an adverse selection.

We think that is the logic of it. But that is not always the case. And we just have a lot of questions around this. But at minimum we would like the same consideration as apparently is going to be offered for the full duals.

DR. MURPHY: I just wanted to add to that. I think maybe states have a lot of experience in this area where, and for instance when one goes out and actually does events and finds seniors that are eligible for our program such as our pharmacy plus waiver which is comprehensive, we frequently find seniors who have been eligible for quite some time and who have had large drug needs.

And yet they unfortunately not known even though we do extensive outreach ourselves have not known about the program. And so you do find a large number of people who have needs and just don't access the programs. And they weren't really trying to gain anything. They were just not able to access.

CHAIRPERSON HENNEBERRY: Thank you. Any additional

comments or reaction to this recommendation?

MR. COSTER: Hi. John Coster with NACDS. I don't know if this is going to fall into this section or if in the next section you are dealing with issues of outreach and education. So if you are in the next section I will sit down.

CHAIRPERSON HENNEBERRY: No. Go ahead. We want to hear your comments.

MR. COSTER: Okay. One thing I wanted to get a sense from the commission of was what you talked about in terms in the role of providers in educating beneficiaries. I would have mentioned this before, but I thought that as you went through this you might have gotten to outreach and education.

Pharmacists interact with beneficiaries every day. And they are probably the ones who are going to get the most questions about the changes in these programs. Some of them may be very concerned about the changes. And the pharmacists are the ones who are going to tell them they are going to change, they are not going to change. This is how this is, you know, going to work for you.

So to what extent did that factor into any of your discussions? For example the states are getting $125 million over the next two years for various activities. Could or should some of that be used to train professionals or educate

health professionals, physicians and pharmacists about the changes? Could some of that be used for education of health professionals? Should some of that be used to pay pharmacists or others to educate?

One concern we had with the OIG's decision regarding the discount program that providers could not be paid to educate or steer, for lack of a better term, to a particular plan. Any discussion about that?

I think there needs to be some recognition that it is health providers, pharmacists in particular, who are going to be interacting with these patients every day. Where do they fit into this whole enrollment, education, outreach process?

So I just throw that out as concerns we have about how this is going to move along. But any insight you can give as to what you discussed there would be helpful.

CHAIRPERSON HENNEBERRY: Now were you listening at the door yesterday when we were deliberating?

MR. COSTER: I was not.

CHAIRPERSON HENNEBERRY: We have had much discussion about this. And I am going to ask Jay if you want to talk about this a little bit. And you will see something alluding to your comments very later in the presentation. But I would like Jay to talk about this a little bit.

DR. Currie: I think, I appreciate your comments.

And we did, we have had discussions of this on a couple of different occasions and about half an hour yesterday at our meeting about it as well.

I think that is one of the lessons that we learned with the discount cards was how much of that burden came toward pharmacists because the patient wanted to get their opinion as to what is a good card for me. How is this going to work? Is this something I should do or not?

And I think that the important part of that is beyond the financial part is the clinical part of that, which is how do I make these healthcare decisions for me beyond the financial. What is this going to mean to my pocketbook? Because they base some clinical decisions in it.

As we work with the new PDPs I think how do we deal with their formularies. Depending on how the SPAPs are set up, how do we merge between the SPAP formulary that may be different than the PDP formulary. And those are going to be very complex clinical decisions for people to try to make to decide what is the best decision for me. And what is, is this a good plan. Is this something I should do?

So we have had quite a bit of discussion about that. I think one of the issues that is brought up is what is that real burden for pharmacy. We don't know.

I think some of us at least anticipate that with Part D going into place it's probably going to be bigger than

what the discount cards. Because that was purely a voluntary program. This one will have a little bit of enticement because of the late enrollment penalties to it. People feel an obligation to make a decision maybe a little bit more than they did with the card.

But then how do you, some pharmacies will be interested in doing that service. Some pharmacies may not. And then how do you avoid any potential conflicts of interest in pharmacists helping people make those decisions.

So we have had quite a bit of discussion on that. I think that is, as you will see later on, that is sort one of our topics that we haven't finished discussing. We will probably entertain a couple of conference calls just about that I am afraid.

But, it is something that we have talked about. And I think many of the states in our previous discussions have sort of recognized that pharmacists were majorly involved in that process with the discount card. And really unless there are some changes within how things are done with marketing and promoting the Part D plans we would anticipate that same issue is going to come back again with the Part D plan implementation.

CHAIRPERSON HENNEBERRY: I think, you know, if you go back to one of our first, I think it was the last bullet on our principles, we have had many discussions, each of the

work groups and the commission as a whole on the broad umbrella issues of education.

And the different layers of education. Both just informing people that the benefit is coming. And then informing people that the benefit is there. And then the importance of everybody delivering messages in the same way and giving the same message.

Because a doctor or a clinician might say something that sounds different than what the Social Security Administration letter said. Or that the Medicare benefits book says. Or a website says. Or the pharmacist says.

So we have recognized the importance of trying to all be on the same page of what is told to potential beneficiaries so they do understand what they are eligible for and especially then, again going back to one of our other tests about how does this impact an SPAP.

If you are fortunate enough to be a senior or a disabled person who lives in the state with a State Pharmaceutical Program that is going to help those benefits even richer then you have another layer of information and both good information and potential confusion.

So we recognized all of that. But we did single out the, very much acknowledged and recognized that pharmacists in many cases are going to have a unique role because of what we know about people's behavior as consumers.

And because of what pharmacists experienced from the discount card.

So we haven't resolved it all. And we haven't come up with our final recommendation on that. But, it's been, we have had many, many, many discussions about it.

MR. SCHUH: I would ask John what his members think in that regard. If you have any comments or suggestions, we are happy to listen to them. As far as education if you have any comments from your members perhaps that you want to share with us we would be happy to consider any suggestions that you have.

MR. COSTER: (Away from microphone.) One of the members on behalf of ---.

CHAIRPERSON HENNEBERRY: Anyone else? Kimberly.

MS. FOX: Yes. I just had a question. And I actually haven't thought that much about this area. But it would seem to me that where the pharmacists' education would be most pronounced is actually in the non-SPAP stage. Especially if we do actually get the auto enrollment and preferred card vendors.

I do think the experience of pharmacists in those states that had it during the discount card period were less difficult than in the states where there were none. So I guess I am just trying to get clarity on that.

CHAIRPERSON HENNEBERRY: We did acknowledge that.

That if there is auto enrollment. I mean if there are, it's less reason for the consumer to be confused about what they are getting and have access to then you are less likely. But I will let Jay explain this more. That it's not as if a senior is going to always just march up to the pharmacist and say well tell me what plan to sign up for.

Those conversations are going to happen within the context of other conversations that the consumer might be having with their pharmacist that are a more natural and logical conversation to be having.

DR. CURRIE: I am not sure how to follow up on that. But I would make a comment that I think it really is going to depend on what do these benefits look like when the SPAPs are trying to merge their benefits with the state programs.

If it's a situation where the SPAP is going to pay for the premium or just fill in all the holes that the PDP, that is pretty much, it's not an issue. If it's a matter of they are going to keep their formulary.

If they are going to have a group of drugs that they do or don't pay for, which may or may not be the same as what the PDP pays for, then I think it's going to become a pretty big issue.

So a lot of this just depends on what the structure of these things end up looking like. And I think at least my

understanding from many of the people from the states around this table is, you know, they are not sure yet what this they are going to do and what their benefit is going to look like when it, you know, in a year and a couple of months from now.

So I think from my perspective I see it if all the states decide we are going to do it the same and we are just going to pay the premiums and then we are out of it, well then it will be pretty simple. If it's something other than that it could be much more complex than in the current system. And so I think it's going to be a state by state issue with what their benefits look like.

CHAIRPERSON HENNEBERRY: Anne Marie.

DR. MURPHY: I also wanted to mention that there are some differences as to the states that have SPAPs. But in some senses and there may be less differences, first of all even in states that have SPAPs, and in Illinois we have both an SPAP and a pharmacy plus waiver, so we have already a current medley of choices for some beneficiaries.

And many people are not even enrolled in them even though they have access to them. And so the fact all those people will need to enroll hopefully in the Medicare drug benefit.

In addition the Medicare benefit unlike SPAPs or our pharmacy plus waiver, there is a late enrollment penalty. And so people need in this instance to make decisions in a

very timely fashion. Unlike other programs where there isn't necessarily always a penalty for later enrollment.

And the more options that seniors and persons with disabilities have I think the more difficult it will also be for them to choose. And I think there are sort of pluses and minuses of all their interactions with their pharmacists or their healthcare professionals.

Or I presume that they would rely on them for some clinical knowledge in regards to formulary choices. And depending on what is offered in the different plans. And so that is different than our situation with an SPAP where there is only one option. It's like either you sign up or you don't. Now when you have multiple choices I think it will be much more difficult.

We have also though discussed that, and given the issues about conflicts of interest and business arrangements between pharmacies and PDP sponsors there may also be some issues there that need to be recognized. And therefore this issue is a little bit more complicated than just uniformly encouraging all interactions.

But I think that the level of choices will add to seniors' needs for interacting with healthcare professionals to assist them in making these choices.

CHAIRPERSON HENNEBERRY: Linda.

MS. FLOWERS: Linda Flowers, AARP. Just another

word to throw into this discussion, which is what do we know about capacity. I mean even if pharmacists need to and should take on all of these counseling obligations are there enough of them out there to really meet the demands of doing what their normal job is and then taking on these extra counseling responsibilities. And Jay maybe you could speak to what the capacity issues have been around the discount cards.

DR. CURRIE: I am not --. I don't think anybody is thinking that a pharmacist should take over this job within the system because there is many people that need to do this job.

I think the issue gets to be more of for those that are interested and have a need and have a population that has the special need and they are in the position to want to do it that we should at least think about them as being a potential asset here.

They are people who understand the people's medications that they are on. They have a working relationship with their providers so they may know how to work around formulary issues. If we have to make a choice, well that is something that I know your doctor and I can get you switched to something that is on the formularies. Things like that.

And they understand insurance. I mean they deal

with insurance all day long. They understand how these programs work, some of those things.

So I don't think that anybody here, and I don't think anybody here, because they haven't told me, but I don't think that anybody says that well pharmacists should take over this responsibility.

We are much more looking at those who do want to help their patients work through this system should at least be considered an asset. And we should be looking to them to be part of the solution, not the whole solution.

I will agree. There is going to be some places where because of the workplace they may not be interested in helping too much. But I know I work with a lot of pharmacists who, you know, they spend an hour with each patient that comes to them for help trying to pick a card.

Well, they are doing some pretty serious education and help in the systems for those people. So I think that the issue gets to be is this an option.

CHAIRPERSON HENNEBERRY: Dennis did you want to add something?

MR. O'DELL: I just wanted to add that I do think that this is an issue of balance. I think it is one where we do want to recognize that there are a number of interested parties that can add value and help bring clarity to what is going to be a very confusing situation.

Maybe particularly in states without SPAPs. And even in those states where maybe the SPAP doesn't choose to auto enroll or takes a different approach. And I think that there can be with everyone working together a balance between the potential financial conflicts of interest and taking advantage of the expertise and the face to face ability of pharmacists and other healthcare providers to interact with the beneficiaries themselves.

I think that oftentimes that contact on a very personal level is where decisions are made. And that no matter how much effort is put in to coordinate it, you know programs to communicate through the normal kinds of media and other outreach, paper, letters, direct mail, et cetera, that in the final analysis oftentimes this population relies on someone that they know personally to help them make that decision.

And I think we should be as inclusive as possible in making sure that anyone that has something that is fair and unbiased to offer is encouraged to do that.

CHAIRPERSON HENNEBERRY: Any other comments on this particular issue? John. Oh, I am sorry. Jim and then Marc.

MR. CHASE: Yes. One other related is we have been talking a lot here about the role of pharmacy around the education and enrollment aspects. But also we have some discussion later about the need to reach out to pharmacists

but other providers as well.

With the implementation of this program coming rather rapidly, I think there will be a need for CMS to help regions coordinate reaching out to providers to explain what is going on. And pharmacy associations will obviously be working on that.

But if we can all kind of work together to make sure the messages get out and it's clear and consistent amongst everyone I think it will help the whole process. So we made some recommendations too about how that needs to be done.

CHAIRPERSON HENNEBERRY: Marc.

MR. RYAN: I also wanted to note that you really need to reemphasize that a lot of this work is going to be done in a two to four month period. And to the issue of SPAPs have their unique educational issues across the board including pharmacists which are sort of the front lines of this.

But I do agree with what Kim said earlier that some of these issues may even be more important in the non-SPAP states. You have MEDSUP issues and things of that nature that I think CMS needs to really think about even beyond the SPAP issue.

CHAIRPERSON HENNEBERRY: Okay. Just a reminder before we take a break, you have heard about our over arching

principles. You have heard about some recommendations around eligibility determination, assets determination, marketing, auto enrollment. The endorsement of preferred plans and non-discrimination, low-income subsidies, premium payments and late enrollment penalties.

So have --. I am going to give you one more chance to comment on this first set of slides and then we will take a break. Kimberly.

MS. FOX: Hi. I am not sure whether it comes here, but I just had a comment about the low income premiums. And this is within the regs as I read them was that the MA-PD plans aren't required to have a basic subsidy. And they raised this in relationship to the dual eligible.

And the fact that they might then essentially only get the subsidy that CMS pays is only the average basic benefit. And so in the cases where people are enrolled in a Medicare Advantage plan they would to pay the additional premium. Is anyone following me on this?

CHAIRPERSON HENNEBERRY: Bob ---.

MS. FOX: And it came up as an issue of duals because they said well, who is going to pay the difference if dual is in a Medicare Advantage plan. And I am not sure the regs actually made a decision in that. I think they sort of threw it out for comment.

But it's equally an issue for the State Pharmacy

Assistance Programs to the degree that their enrollees are in Medicare Advantage plans. And then the states are going to be beholding to paying whatever the plan, whatever minimum benefit is above and beyond the CMS subsidy.

MS. SCHOFIELD: Are you saying that they would only be paid up to the average? You know how there is that average limitation.

MS. FOX: Right. The average basic benefit. But the MA-PD --. There is a different standard set for the MA-PD plans and the PDP plans. They don't have to both, in the case of the PDPs they actually have to provide a basic standard benefit.

In the case of the MA-PDs they are not required. And I am just raising it as a potential problem for states that have a lot of Medicare Advantage enrollment because it will mean that the states will have to pay that difference between what CMS will pay and the MA-PD.

So to the degree that states are concerned about that they may want to comment on why there is a difference between the PDP and the MA-PD plans and whether you want to weigh in on that. Because you are basically at risk.

CHAIRPERSON HENNEBERRY: Bob, do you want to say anymore about that?

Mr. Power [who is Ms. Palmer??]: I agree. And it's not part of our report so far because there are so many

details of this kind. That particular one didn't happen to rise to our list. But I think you are right. We should probably include it.

CHAIRPERSON HENNEBERRY: Great. Thank you for bringing that to our attention. Okay. We are going to take a 15 minute break. And come back at ten til 11:00.

(Whereupon, a brief recess was taken.)

CHAIRPERSON HENNEBERRY: Sybil, could you just do me a favor and just help people out from the hall. We are starting. Thank you. Okay. We are going to move into the next set of recommendations.

We will follow the same format. A commission member will present the recommendations and the background. And if members of the audience want to comment or ask for clarification or other commission members want to comment we will do that.

I will mention this again at the end, but just a reminder that all of these recommendations are really part of the final product of the commission. And that will be a full report. And the design of the report will have the background of the issue, the recommendation of the commission.

So what you are seeing up here is really just pulling out, if you will, the specific recommendations in bullet form. There is a lot of information and background

that will surround each of these when you see them in our final report.

Okay. I think first up here is network design. And that is Laurie.

Workgroup Two - Coverage and Access

Drug Coverage and Service Delivery

by Laurie Hines, J.D.

MS. HINES: I wanted to start out by acknowledging that this is the work of workgroup two and our chairman and leader of the workgroup was Linda Schofield and continues to be Linda. And I want to thank her on behalf of the workgroup for her incredible organization skills and for keeping us on task in some pretty complicated territory.

Under the first slide, the first recommendation is a response to CMS' proposed regs that currently propose to allow a PDP sponsor to have any combination of preferred and non-preferred pharmacies to comprise an adequate pharmacy network in terms of meeting the geographic access standards.

The non-preferred pharmacies by definition are pharmacies that would have a higher cost share that would impact the enrollee as well as the SPAP who is going to wrap around.

Even CMS in their background to the regs expressed their concern that this combination could end up with some PDPs proposing a plan that would essentially either

intentionally or unintentionally discriminate against people in certain geographic areas. Forcing them in such a high cost plan to not be able to sign up for the particular plan in their region.

So given that concern the commission shares the concern that CMS expressed. And while it may not be a great likelihood that that would happen, we believe the risk is great enough and the consequences are great enough that our recommendation is that CMS should change their proposed reg to only allow preferred pharmacies to count as part of a plan's network for the purposes of determining whether a plan meets the CMS access standards.

The second recommendation, again CMS in their background asked for comments as to whether they should strongly encourage or require that PDP sponsors networks include long term care pharmacies.

We as the commission came down on the side of requiring PDP sponsors to solicit any willing long term care pharmacy in their region to join their network. We believe that it's critical that the long term care pharmacies that have exclusive contracts with facilities and group homes and those sorts of institutional settings that those pharmacies must be in the network.

Simply because otherwise these are people who cannot easily get up out of their facility and go shop at

another pharmacy. So we are requesting that CMS mandate or that PDP sponsors solicit and contract with any willing long term care pharmacy.

The third recommendation, again, CMS in their regs and in the background they admit that they narrowly defined long term care facility to only mean nursing homes and skilled nursing facilities. And they asked for comments about whether that was a broad enough definition.

The commission's recommendation is that that is not a broad enough definition and that long term care facilities should include ICFs/MR, intermediate care facilities for the mentally retarded for those with disabilities, and other institutional or group housing arrangements. So that again with regard to long term care pharmacies there is adequate access for people in these facilities.

Those are our recommendations that are specific to network ---.

CHAIRPERSON HENNEBERRY: Any additions or comments from commission members or questions from the audience?

MR. COSTER: I promise not to speak on every one.

CHAIRPERSON HENNEBERRY: Oh, no, no, no. That is why we are here.

MR. COSTER: In terms of the pharmacy network design, just we could not agree with you more that in designing the network that the plans have to meet the TRICARE

access standards for preferred pharmacy.

And as you know the proposed reg would allow them to shrink that down to a smaller preferred network than TRICARE, which when you combine that with fact that you can average across the urban, suburban, and rural areas could, even if they adopt what you said, could create access problems for beneficiaries.

And I guess a lot of this depends upon whether the SPAP is going to be offered in more then one state. I don't know if I can explain this other than to say the Part D plans have to be offered in the entire region.

So if there is an SPAP in a state would that, would you say that the Part D plan has to meet the access requirements for that state? Or for the entire region? In other words if you have multiple states in a region they can average the access standards across the urban, suburban, and rural areas.

Would you require for example if there is a region consisting of New York and Pennsylvania or New York, New Jersey and Pennsylvania, where the three biggest SPAPs are, that the SPAP would have to meet the access standards in each state in each region? Or across the entire region? Because that would bear significantly on whether you would have 90 percent access in urban areas and 90 percent in suburban and 15 percent in rural.

So I just throw that out as another potential consideration for the commission to make some recommendation regarding how they have to use the standards in each of the urban, suburban, and rural areas in that state.

CHAIRPERSON HENNEBERRY: Do any of the group two members want to comment on that?

MS. SCHOFIELD: I would like to ask you to educate us a little more on that. As I understood the proposed regulations there are access standards for urban and suburban. But I didn't understand that they would take all urban areas in a huge region and lump them together.

I assumed it would be like Medicaid plans usually are tested for network access. And they have to show a geo-access mapping process so that almost on a zip code level or some other fairly refined basis in each area they have to meet whatever the access standard is that applies to that area, whether it's urban, or suburban, or rural.

And are you saying that all rural areas across an entire region, so you could have one rural area with absolutely no pharmacies in it and another rural area with loads. And they would average out. That strikes me as surprising and scary.

MR. COSTER: Yes. I think we have done a pretty good analysis of the access provisions in the proposed reg. But say for example the entire region of New England is one

region. You could have, and I have never designed a network, so I am doing this all on theory.

You could have 95 percent urban access in Boston. 95 percent in Hartford, 75 percent in Burlington, 70 percent in Portland, Maine. But on average if all those areas are urban as long as that meets 90 percent, 90 percent of beneficiaries in urban areas are within two miles you meet the access standards.

MS. SCHOFIELD: Okay.

MR. COSTER: Same thing for suburban. Same thing --.

MS. SCHOFIELD: I assumed it was within each zip code --

MR. COSTER: No.

MS. SCHOFIELD: -- that it would be tested.

MR. COSTER: It's across those areas. Now, I won't go into a long dissertation of TRICare which are the access standards on which this is based doesn't do it that way. So, our view is what they have created is a standard that doesn't even meet the TRICARE standards.

MS. SCHOFIELD: So TRICARE doesn't, does it across an entire region? Or do they --?

MR. COSTER: They don't have regions. I am sorry. TRICARE is a nation program. And they do average. But when they have 53,000 pharmacies in their network which is almost

all retail pharmacies in the United States.

We would argue that when they meet the, when they look at the access standards CMS has to assure that Part D plan meet the standards equal to or greater then TRICARE, which means they should determine whether or not proportionately in a region there are that many pharmacies in the network.

But for the purposes of what CMS has laid out you can average them across the region. And we don't know the regions yet. And as you know they are looking at anywhere from ten to 50 regions. But one thing you would have to consider is if there are multiple states in a region whether you want to make some recommendation about, in the state of New York, whether they have to meet 90 percent in each, you know, in all urban areas in New York State or in each urban area in New York State.

MS. SCHOFIELD: Thank you. That is very helpful.

MS. NAGLIERI: If I might --

CHAIRPERSON HENNEBERRY: Julie.

MS. NAGLIERI: -- make the point that the commission did comment in their comments on the regulations to not directly address this issue, but we did make comment in favor of more regions than less to address some of the states' specific concerns.

So that we would see plans that were more suited to

the state or region that they would be functioning within.

MS. SCHOFIELD: But I would add that even within a state, particularly for our population, we are very concerned about discrimination of multiple types.

You don't want to have inner city areas for example be left with nothing but non-preferred pharmacies or be designed so that you can kind of avoid Bridgeport and only cover Hartford because maybe they have a different kind of population or something. So I appreciate your comments.

CHAIRPERSON HENNEBERRY: Kimberly.

MS. FOX: I would totally concur with what he just raised. And I think that actually in the preamble they actually asked for comments on this specific issue of how to define geographic access by average within a region. So it definitely seems like a good thing for this group to at least comment.

And the other question I just had is I think that even the decision or within the regs having preferred pharmacies was something that CMS, I don't think it's required in statute. But it was something that CMS sort of entered in upon sort of in response to any willing provider concerns.

And I guess I am just asking you, it seems to me that the preferred pharmacy element is going to be increased coordination of benefits problems for the SPAPs considerably

to the degree that they have to be knowing who is in the preferred, non-preferred. Knowing all the different co-payments. I mean it just again increases administrative costs exponentially.

So I am just sort of wondering why you guys, you could just weigh in and say you don't support the idea of preferred pharmacies. And I just wondered why you didn't do so.

MS. SCHOFIELD: It's a good point. I mean we didn't come flat out and say that we don't agree with it. But we certainly had exactly those concerns. Not only for the SPAPs as it complicated, but for the average beneficiary. I mean if you think about that you might have a plan with three or four co-pay tiers and that those co-pay tiers can be modified once again doubling the number to have differences between preferred and non-preferred.

And then it once again be modified for mail order drugs. You have this exponential growth in co-pay tiers. People showing up at the counter are going to have no idea what they should expect to pay. And they are never going to understand whether their pharmacist has calculated it correctly or not for their plan. It's going to be quite confusing for them.

And similarly for the SPAPs who are going to end up paying that co-pay amount, which complicates something we

come to later in the appeals section. You know, do you know whether you can appeal a co-pay or not, you need to know which tier you are in. How the heck are you going to know that with all of these multiple kinds of co-pay issues.

Yes. Thank you. I appreciate that. And that is something we should talk about too. Just recommending against it.

CHAIRPERSON HENNEBERRY: Okay. Any other feedback or comments on the network design?

(No response.)

CHAIRPERSON HENNEBERRY: All right. And Laurie, you are up with mail order.

Mail Order

by Laurie Hines, J.D.

MS. HINES: As you may know the proposed regs from CMS allow for, as does the MMA, allow for mail order as an option for PDP sponsors to offer to their enrollees. But they are also required to offer an extended supply at a retail pharmacy so that people can opt-out of mail order but can still get an extended supply at their pharmacy.

But they will have to pay the cost difference between the mail order cost of their sponsor and the retail pharmacy extended supply cost.

We want to simply make sure that CMS allows that cost differential. Whether the senior pays it or an SPAP

pays it by wrapping around or coordinating. We want to make sure that that amount goes toward their true out-of-pocket, which I think will be referred now on as “TrOOP”.

And you are probably -- the TrOOP is simply what a senior or fortunately an SPAP pays toward their drug costs that will of course the more they pay out-of-pocket the quicker they get to the catastrophic benefit. So we simply want to make sure that that cost does apply toward TrOOP.

The second recommendation is with regard to mail order the commission had some detailed discussions with regard to our population. In particular SPAP populations who tend to be very old. I think most of us our average age is probably 80 in terms of our membership. Somewhere between 78 and 80.

And so we are talking about seniors who are lower income and very old and could potentially have an unsecured mail facility or mailbox. And we are concerned that prescription drugs would be mailed to them on a regular basis could be stolen from the mailbox.

So our second recommendation with regard to mail order is that CMS should encourage PDP sponsors to have an exception process by which a senior can opt-out of the mail order provision that is cheaper for them and opt-into the extended supply at retail.

But not have to pay the cost differential if they

can show that they in someway, and we didn't have a specific proposal with regard to this, but the PDP sponsors should have some waiver process some way by which the senior can assert that they have an unsecured place for prescription drugs to be mailed. But that they should still get the same cost, or the same price.

CHAIRPERSON HENNEBERRY: Any comments or questions about that recommendation?

MR. CHASE: Joan, I would just point out that this was one of the areas where we did a lot of discussion about whether some members felt that mail order is not right for the SPAP population and others felt differently.

So I think the way we worded this was important to not say it shouldn't be done. But there should be some way to encourage the PDPs to have some exception process so it doesn't say it's not appropriate in certain cases and that it could be done in certain cases.

MR. EDWARDS: Clayton Edwards from Medco. I guess my first question would be what is the commission's definition of insecure as far as a mailbox? Medco mails around 100 million prescriptions per year to people. There is very, very low incident of people saying my orders have been stolen.

So, I guess I would challenge the commission to go back and really look at this. How would you measure what is

insecure? How do you validate what is an insecure mailbox? I would say I have an insecure mailbox. It's just a mailbox at the end of my driveway versus something in a Mailbox Etc. where someone would sign for everything and put it in locked box that you would walk into the store with.

And I would bet that most of the people in this room have the same kind of mailbox that I do. So, by definition I think that is saying that I should be able to opt-out of something that as a PDP can derive some significant cost savings.

MR. CHASE: Joan, I could try to address part of that. Which is there was some, I was one who didn't feel as bad about your point of mail order can be secure. But I think what is important for us and the reason why we put this here is with the SPAP population we have to recognize there are people who don't have mailboxes at all.

And so it's a disadvantage to say that somehow the benefit would be differential for people who can't get drugs mailed to them at all. And that kind of led us. And others felt like well, there are people who because of their situation even though they do have a mailbox, it might not be secure for them.

But I think what we could agree upon is this is a different population where mail order may not always work and there needs to be some kind of exception process for those

who mail order is not appropriate for.

CHAIRPERSON HENNEBERRY: And I think we did acknowledge that the number might be small. But for the population for the 80 year old widow who lives by herself in a not so safe environment that she or he should have access to that exception. But I think we did acknowledge that we are not, we probably are not talking about huge numbers of people.

MS. SCHOFIELD: I would just, as an anecdote from my old experiences as a Medicaid director, we had patients who had home health visitors, you know home health nurses who would bring supplies with them and try to leave a one week supply of things like bandages.

I mean who would steal bandages? And they would be stolen from folks who were living in housing projects. So that the nurses always had to bring supplies with them every time. They couldn't just leave a supply there.

So, yes your mailbox isn't locked. Mine is the same. Mine is perfectly secure. I mean people could leave me gold in my mailbox and it would stay there. But it's not about how the mailbox is built. It's about the neighborhood. And there are some neighborhoods where you just don't want to leave anything loose, hanging around. Especially not something that says Medco on the outside.

And we didn't have a good idea exactly how to

define that and would welcome your input. If you have examples of the kinds of instances where people from your experience have had things stolen. My guess is that you haven't, Medco hasn't been sending mail order drugs to this particular kind of population.

You know, a formerly Medicaid, currently SPAP, kind of population. And that those experiences will be different then the middle class folks that you have traditionally served. So we just wanted to be sensitive to the difference in that population group.

CHAIRPERSON HENNEBERRY: Well and I think one of the issues Linda raised, I mean that is an alternative for you all and other companies to think about. And I don't know how your packaging is. But, that might solve half of this problem. Although there are places where it wouldn't matter what the box says. Anything is going to get stolen. So.

MS. LIVERATTI: Joan.

CHAIRPERSON HENNEBERRY: Go ahead, Mary.

MS. LIVERATTI: I just want to make a quick comment on that. That in Nevada 95 percent of our people go to pharmacies to get their prescriptions. And five percent are using mail order. And I think there is some self selection that people know that if they are not going to receive that mail order they don't even attempt to get it delivered. So I would just offer that.

CHAIRPERSON HENNEBERRY: Yes.

MR. COSTER: Joan, I promised not to comment on every slide. I am kind of breaking my promise.

CHAIRPERSON HENNEBERRY: We wish you to.

MR. COSTER: But these are like key issues that we care about. So, we would agree with both of the recommendations that you have up there. I guess I would further add was there any discussion regarding what cost differential means?

Because the statute says the pharmacies, plans have to allow retail pharmacies to supply, provide similar quantities of medication at retail if they are provided through mail with any difference in charge being paid for by the beneficiary.

The reg has interpreted that as a difference in negotiated price which is essentially, I think, the network rates between retail and mail. One issue we were very strong about in our comments was that the plans cannot institute differential cost sharing between retail and mail.

In other words the only difference between a retail prescription and a mail prescription in terms of cost to the beneficiary is the difference between charge interpreted as the difference in negotiated price.

But a plan can't use a ten percent retail, a ten percent mail and a 20 percent retail cost sharing. The reg

is conspicuously silent on that. And as you know plans can create cost sharing that as long as it is actuarially equivalent to whatever the standard is for that year they are okay.

So I don't know whether there was discussion about that or if you entertained discussion about that. But we were very strong in our comments in that beneficiaries cannot be induced to use mail through economic incentives.

I think most SPAPs as far as I know have very low use of mail order. In fact most of our data suggests that if you give beneficiaries the equal choice the overwhelming majority will use retail pharmacies over mail.

So I throw that out as another potential option. Because this whole concept of what the cost differential is still kind of squishy to me in terms of what CMS might do with that.

CHAIRPERSON HENNEBERRY: Thank you. Marc.

MR. RYAN: This was one issue I think I had raised in our work group. And I admit it was very controversial, but I think it's a good point. And to talk about it from the SPAP side depending on the difference between the discount at the retail level and at the mail order level this could in fact be a significant cost issue in my view to SPAPs.

It might very well be that depending on the difference in the negotiated discounts at the mail order and

what State Pharmaceutical Plans historically get through rebates and they will be losing some of that in this process. If the SPAP is picking up the difference between the retail discount and the mail order discount it could be fairly significant to states.

So I think it's a good point that needs to be fleshed out. I understand the philosophy behind what is being done. And I think from a cost sense makes sense. I also think states need some protection as that is all worked out as we move down the road.

CHAIRPERSON HENNEBERRY: Okay. Any other comments on mail order?

(No response.)

CHAIRPERSON HENNEBERRY: Okay. Laurie, multiple residences.

Multiple Residences and Travel

by Laurie Hines, J.D.

MS. HINES: Most of the SPAPs around the country have current policies for their current membership with regard to travel. If you are on a holiday or vacation how you get drugs. Some restrict that. Some have very specific policies.

Most SPAPs as well have legislated who can be a member in their program. And typically it is only residents of that state who will get the state benefits in the SPAP.

To some extent that goes back to how the regions are defined. Obviously I think our preference is that regions are defined by state boundaries. So it makes it easier for SPAPs to maintain their membership with regard to who is a state resident.

The CMS regs allow for dis-enrollment from PDP sponsored plans under a variety of circumstances. One of which is a proposal if the member is out of the region, or living out of the region for a certain period of time.

Our recommendation with regard to that was simply that PDP sponsors notify SPAPs of any dis-enrollment or enrollment changes that have impact upon the SPAP member. We don't want to leave people without coverage for any period of time obviously. So we need to know about enrollment changes and particularly dis-enrollment.

With regard to travel benefits we were pretty loose on this in terms on this in terms of we simply want to know what the PDP sponsors' policies are with regard to travel benefits.

Again, SPAPs know that we may have some state policy decisions to make once the regions are formed, once the sponsors are out there, once we see the plan specifics. We may have legislative or rule making or just policy decisions to make with regard to how we currently run our SPAP as opposed to how we manage it after January of '06 with

regard to how strict we are about residency membership, how we deal with travel benefits.

So we made the recommendations fairly specific just with regard to good communication between the PDP sponsor and the SPAP.

CHAIRPERSON HENNEBERRY: And I do want to clarify for the audience we are not talking about well off people who have a home in the north and a home in the south and a home in the Caribbean. We are talking about people who spend some time with family members in one part of the country and some time with other family members in other states. So that was our concern.

Any reaction or comments or questions about this?

(No response.)

CHAIRPERSON HENNEBERRY: Okay. Now we get into some fun stuff. Formulary issues. And we have two slides on this. So Marc why don't you, we can just go through both of those I think. And then we will take comments and questions after.

Formulary Issues

by Marc S. Ryan, M.P.A.

MR. RYAN: Sure. Thank you. In a general sense in 20 seconds or less leading to the six or seven bullets on those two pages we wanted to stress that we recognize what we are trying to do here is balance the need to contain costs

through the use of formularies which is pretty clear in the MMA.

But also protect continuity of care, ensure minimal disruption for clients, and honestly reduce some potential cost shift to states that could incur intentionally or unintentionally as this is implemented.

On slide 18, the first bullet here, this looks far scarier to some people then it really is. Basically, if you look at the rule essentially CMS would clearly have some very early on ability to actually look at formularies and things of that nature.

But as you move throughout the process maybe there are changes and things of that nature. It's much looser. What we are trying to propose here is not by any means an iron clad rule. But simply ensuring that as you move along in the process throughout a benefit year for example that for example if 90 percent of people covered with certain illnesses and that is just one benchmark we would think about would be required to switch medications along the way that it would trigger a review by CMS along the way.

It wouldn't be an absolute approval but CMS would reserve the authority to essentially look at those along the way if there are concerns. We don't think it's very clear in the rule right now. So again it's not a strict dictate regarding the formularies and the approval along the process

of these. That would take away a lot of flexibility. But it would be allowed. It would be acceptable for CMS to do that. And I think it would go to address some of the concerns that states have regarding that.

The second area --.

CHAIRPERSON HENNEBERRY: Marc, do we --. I think we need to clarify. We meant that 90 percent of the people shouldn't have to switch. Right?

MR. RYAN: That is correct. 90 percent shouldn't have to switch. That is correct.

CHAIRPERSON HENNEBERRY: Okay. Thank you.

MR. RYAN: On item number two this was sort of in a general sense, it's obviously given the fact that formularies are not established yet we don't know exactly what they will look like. It's difficult for us to propose any iron clad rules regarding what we would like to see in terms of absolute issues in terms of integration with SPAPs.

But in a general sense we are trying to stress throughout that we need very important coordination with the PDPs and MA-PDs. And although we seek guidance in the law and guidance in the regulation we do not see what we believe is the real strong language we need to accomplish that.

And frankly one of the reasons that we are worried about this is we really do believe there is a risk of SPAPs not coordinating benefits to the degree we would like to see

at the state level.

MS. SCHOFIELD: Can I just jump in?

MR. RYAN: Sure.

MS. SCHOFIELD: This was in part also about recognizing that if formulary is not adequate and the SPAP looks at a plan and says geez our patients in most cases are not going to have their drugs covered and we are going to inherit the costs for that anyway, that the SPAPs may choose not to buy in to some of these PDP plans. That was one of the points that people made yesterday.

MR. RYAN: Okay. The third issue CMS should establish transition rules. Many states that have lived through the fallout of implementing en masse preferred drug lists, formularies, prior authorization, generic substitution, I think we know first hand some of the complications that you really end up at.

And frankly if you look at the implementation as of January there is the potential to run into these same types of issues as Part D is implemented in January. And it becomes even more complex when you are thinking about states wrapping around that plan as well and multiple issues of oversight and authorization.

So we are recommending here some transitionary rules that could even go to the issue of a 90 day phase-in for example, just one idea out there that would allow any

prior authorization, any change over in drugs to occur for those SPAP recipients. Because we think the continuity of care may be very important.

And again with the short time frame from say September to January in a general sense of implementation in the plan those kinds of things are going to be very important from all levels, from the pharmacist up to the SPAP and up to the PDP.

And again we would emphasize there that the coordination is essential in that time frame as it is on an ongoing basis.

The fourth area on this is CMS should reserve authority to review formulary changes to ensure continued compliance. Under the rules CMS would approve formularies and have limited oversight. It sort of ties into the first bullet.

We believe to protect the SPAP programs and patient health that CMS should reserve the right to review changes once the initial approval has been granted.

Moving on to the next slide, this is a little bit more controversial. I can't say we exactly are total, as a commission we are uniform in our opinions on these areas. But in a general sense we have sort of given a tiered approach to a concern that we have.

And we believe strongly as sort of advocates at

least in the state side and also clearly on the private side that the most important thing here is really to protect the adverse clinical outcomes that could occur in this very complex environment when you are dealing with multiple programs here.

Some members of the commission feel strongly that individuals should not be subject to mid-year deletions on a formulary. That if they are on that drug that they should have that right for that benefit year to maintain that. And again it's not entirely uniform on the commission. But we point that out that there is that view out there.

We recognize that we --. We also want to have flexibility in preferred drug lists in our own programs. But nonetheless some of us do feel that mid-year deletions should, that individuals should not be subject to that.

DR. MURPHY: I just wanted to also add that when we discussed that we exempted out from that. Obviously if a generic comes on the market we fully support substitution of direct equivalents.

And so there are other instances where there might be a safety issue with the drug. And obviously we fully support removal of unsafe drugs from formularies. So that wasn't an unqualified no deletions, never, no how.

MR. RYAN: Right. The safety issue, obviously generic substitution if it's generically equivalent makes

sense as well as nothing would bar a physician from wanting to change an individual to another drug in that same therapeutic class.

So again there is not absolute consensus on that first mid-year deletion. Where I think the commission gets much closer to consensus is the issue of potentially grandfathering existing patients onto those drugs for that benefit year.

And also after that as a further default the rule speaks to the issue of a 30 day notice period. We believe that that is really insufficient for both SPAPs as well as for individuals of the time they would need to go to the doctor and be counseled about another drug that is on the formulary or potentially appeals issues and things of that nature. So we would recommend a 90 day notice.

Tying into the next bullet mid-year changes affect the SPAPs' ability to coordinate benefits. Again, beyond the continuity of care issues. I think the 30 day issue really comes in here because it's probably physically impossible for SPAPs to make the type of programmatic and other administrative changes they would need to make if they only have 30 day notice in terms of whether they are going to end up covering a drug that for whatever reason is dropped from the formulary.

So we wanted to stress that this goes beyond just a

clinical issue. It becomes an administrative issue in some ways for us to react to that 30 day notice if you are an SPAP.

The last issue that we want to cover here is really the issue of in the proposed rule, CMS has requested that they would really like to get some opinions and it went through the regulatory comment period regarding special needs issues.

And we recognize that many states, and we are not arguing that all special needs population should be exempt from any type of formulary design. We don't do that as a matter of practice consistently at state levels. For example if Medicaid plans have formularies or preferred drug lists.

However, we did want to sort of state emphatically and I think we will be fleshing this out a little more as we move forward that we agree with CMS' concerns especially in the preamble that certain populations' needs for continuity of care really trumps the issue of formularies.

So we are not calling for outright exemptions necessarily for all groups. But we do recognize that certain special needs populations like those that are mentally ill, AIDS populations, certain long term care populations certainly need to have the open formulary or less restrictive formularies than may occur in Part D plans.

And so we recommend to CMS that they really keep an

eye on those issues. Later on we talked a little more about institutionalized populations regarding cost sharing which is also a concern. But we will be looking at that later.

CHAIRPERSON HENNEBERRY: Thank you. Any other additions or comments from the commission?

(No response.)

CHAIRPERSON HENNEBERRY: Clarifications or --. From the audience? Any questions about this?

(No response.)

CHAIRPERSON HENNEBERRY: Oh, come on. There are two slides. You must have some questions or a response. No. Okay. All right. Well, following --.

MS. FOX: I really am seeming like I am talking too much. But I actually just had a question and I don't have a recommendation. But U.S. Pharmacopoeia has come up with its guidelines. And is this commission planning on, because I know there has been a lot of controversy from both sides, which I guess means maybe they have reached a good compromise.

But whether the SPAP transition commission plans on weighing in at all on those proposed guidelines and rules since many of the PDPs are likely, well we don't know. They won't necessarily use them. But they are going to be a major standard in the field. So I am just wondering if you guys are going to comment on --.

MS. SCHOFIELD: We heard the comment period for USP has closed. But they are in the midst of revising their recommendations. I at least have heard that they have already informally suggested that they would include the classes. But maybe only one drug in each class which doesn't actually comport with the law. So, I am kind of confused by that.

And CMS has also indicated that in spite of USP safe harbor provisions that they would be looking at formularies to assure that they did not discriminate against people with any particular illness. So, I think at this point we are kind of waiting for what comes out next.

But I would underscore what Marc said at the outset of his comments that the access to an adequate formulary is critical for a multiple, for multiple reasons.

Not as advocates for this low income population you have a lot of people in this group who have rare diseases, who have very complex multiple co-morbid situations where they are not using sort of typical types of run of the mill drugs.

And, you know, different age groups that have different tolerances for medications. That the need for a broader formulary is significant from a clinical perspective. And we are also very concerned about the potential for absorbing the cost shift if the formulary is tight and the

SPAP winds up paying for all those drugs that are not on the formulary.

A third issue is that dual eligibles although they are not currently SPAP beneficiaries if they are enrolled in these PDP plans and don't have access to the drugs that they need and cannot fall back on the Medicaid plans, we fully expect that many of them will begin to enroll in the SPAPs in order to get that kind of wrap around coverage.

So we are concerned that this could create an incentive to actually make the SPAP programs bigger and more costly for the states if the formularies are not adequate. So, it's a very, very big issue to the SPAPs.

MS. FOX: I guess my only comment is that --.

MS. SCHOFIELD: You need to use the mike so she can get it on the tape.

MS. FOX: I am not very well versed in the USP guidelines. But having just had a meeting with states last week where we had a presentation by someone from Harvard about it, the slippage is also between, I think, between that there is below the class there is a subcategory. That is the big issue that people are --.

MS. SCHOFIELD: Yes. And that is what I was saying. That the USP is now indicating informally that they will make a recommendation about including those classes as opposed to subclass --.

MS. FOX: Subcategories. They left it as option.

MS. SCHOFIELD: Recommended subdivision. That is the right term. Thank you.

CHAIRPERSON HENNEBERRY: Okay. Any other questions or comments on formularies?

(No response.)

CHAIRPERSON HENNEBERRY: All right. We are going to try and get through denials and appeals before lunch. Another dense and complicated area and I think in our NPRM comments this had to be at least six pages, I think. It was a really important part of what we had to say. So Linda is going to take both of these slides. And then we will have comments.

Denials and Appeals

by Linda J. Schofield, B.S.N., M.P.H.

MS. SCHOFIELD: And I am going to really try to just hit high points and not go into all of the details that will be in the reports and was in the original, in our NPRM comments.

It’s an extremely critical issue to the SPAPs because in conjunction with the formularies the appeal process really is dealing with will people have access to the medications that they need. So it’s a very key beneficiary protection issue.

And we fully expect that the formularies that these

private sector plans will have will be different and more restrictive then the kinds of formularies that people have based in their SPAPs and in their Medicaid programs.

Our concern going back to our over arching principles which is how do we preserve uninterrupted access to medications for our beneficiaries. That translates into a couple of concerns for the SPAPs in general about the appeals process.

First, if an SPAP is a full benefit SPAP that SPAP will pay for non-formulary drugs. So people will have continued access but the SPAP costs, as I highlighted earlier, could be substantial. Even during the appeal process.

So making sure that people have adequate appeals and access is critical from a cost perspective. And then again from an access perspective there are many SPAPs that probably will not provide for coverage of non-formulary drugs but in their consumer advocacy roles they are concerned that their patients, their beneficiaries, will be going without necessary medications or will be switching to drugs that may or may not work as well for them.

Let’s see. I just want to remind you, I am sure that everybody in the audience knows that there are appeals that are both related to access for non-formulary drugs or other drugs that are otherwise denied through a utilization

management process like step therapy. And there are also appeals for co-pay tiers. So two different appeal processes.

The first recommendation is that CMS should recognize, I am looking for my own paper here. Should recognize the SPAP's authority to encourage enrollees to enroll in a particular plan.

This goes back to comments that Julie and Susan had made earlier about wanting to be able to prefer and auto enroll into a plan. Clearly SPAPs have an interest both a cost interest and a consumer advocate interest in making sure that their beneficiaries enroll in plans that have the broadest formularies and will cover their needs most effectively so that they don't wind up inheriting the rest of that cost or having patients who don't get their needs met. And so this is just one more reason to support that earlier recommendation.

We also want to make sure that SPAPs are given authority to appeal on behalf of beneficiaries. The SPAPs, whether they are a full benefit SPAP or just a Medi-Gap kind of SPAP will be inheriting some of those costs. Either paying for the non-formulary drugs or paying for the co-pays if they are only a Medi-Gap kind of program.

And so it's very important that the SPAPs have the ability to appeal on behalf of the patients because the patients will have no incentive to appeal. They are going to

get their medication covered in full anyway.

The SPAP holds the financial responsibility and needs to be able to appeal. And there is language in the proposed regulation that is concerning to the SPAPs because there is a phrase that --. Well, number one there is a section about authorized representatives. We would like the SPAPs to be clearly considered to be an authorized representative without having to go through some onerous legal process to be named as authorized representative for every individual. It would just simplify things.

But also there is a phrase in the proposed regulations that states that if beneficiaries have no liability to pay that they cannot appeal. And that would in essence could be interpreted to prevent an SPAP from ever being able to appeal anything for a beneficiary that they are covering. And obviously that is not appropriate. So that is the second recommendation.

Our third recommendation is to recognize that this is an older population, a disabled population. People with mental disabilities, with cognitive impairments. That they are going to turn to their traditional care givers, their pharmacists and their physicians for help, and this is broader than just the SPAP, when they need to appeal.

And in the proposed regulations a physician can initiate an exception request at the first level of

exception. They cannot initiate anything beyond that unless it is an expedited redetermination. That is the only thing they can have a role in.

And the pharmacists do not have a role in exceptions or appeals at all. And even though they have often had a role in prior authorization and appeals processes in other kinds of plans.

So the SPAPs want the traditional care givers to be able to have a role to participate immediately in assuring that the patients have access to care. It might relieve the SPAPs of some of that responsibility as well.

We looked at a number of different options, I won't go into all of them, for how we could reduce patient risk of a denial and of lengthy appeals process. As noted earlier, having a rule for pharmacists in contacting the physicians for alternative drugs or contacting the PDP to seek an exception is one way.

Another issue which actually the lady from AARP mentioned at our initial meeting was that we should mimic some of the Medicaid kind of benefits for our populations for the low income folks, assuring that if they would be denied at the pharmacy counter that they would be given a three day emergency supply at the discretion of the pharmacist.

And that during the appeal process they should have continue access to their medications. Keep in mind that the

duals certainly have that now. If their drug is not on the PDL and they appeal, they can continue to get that drug covered until the appeals are resolved.

For low income folks who do not have the financial wherewithal to pay out-of-pocket for what could be many months of an appeals process for an expensive drug, you know denying and assuming that they are going to appeal is really tantamount to preventing them from having access to potentially life saving drugs. So we are putting them at huge risk of medical catastrophe if they don't have some sort of protection.

We also looked at allowing, enabling the SPAPs to, we are suggesting that a new appeal process be put in place so that the SPAPs don't have to appeal every single individual claim. But could look at a pattern of denials if there seems to be a problem repeatedly with the same drug and the same PDP that perhaps a SPAP could seek to resolve that with the PDP.

And failing that, go to an external review organization to resolve that situation where there is a demonstrated pattern of medical necessity for a drug that is being denied.

Let's see. Am I on the next one? No. Bottom one. Written denial notices. We are very concerned about the lack of notification for beneficiaries particularly in the case

where an SPAP is not going to cover the formulary, the non-formulary drug, that the individual when he goes to the counter under the proposed regulations would get no notification of why their drug is denied or what they could do about it to appeal.

The lack of knowledge on behalf of beneficiaries is enormous. People do not know that they have appeal rights even though they have been told that when they enroll. Even in private plans that is well documented that most people do not understand that they have an appeal right.

And even if they do, they don't know the 800 number. It's not inscribed or on the back of their eyelids to remember that you call such and such a number to appeal. So they need to have timely information. You know that sort of teachable moment is when you have just been denied you should get information about what can you do about it.

If the SPAPs are going to be appealing on behalf of that person in the case of a formulary denial, then the SPAPs also need to be notified of the denial and the reason for the denial. And that might be something that could be achieved through a cross over claims process that includes information about the reason for denial.

Because in some cases the SPAPs would not want to, and indeed the beneficiaries would not necessarily want to appeal. If it's because they come in a day early for their

refill, well, we will just wait a day.

Or if it's because the drug is no longer safe or, you know, there are many reasons why an SPAP or an individual might think, well, gee, I shouldn't appeal that. They need to know what the reason is that the drug was denied. If it's for non-formulary they may well want to appeal that.

On the next slide time frames are of a big concern. The time frames are very lengthy. I won't go into all the details. But for an individual who has paid for their drug out-of-pocket the initial exception process can be 30 days. For a person who has not paid out-of-pocket and is suffering without the drug, they can appeal and be addressed within 14 days.

Those kind of 14 to 30 day time frames are very lengthy for an individual who is on a chronic medication that they need to sustain their health. And particularly if they can't afford to pay for it out-of-pocket.

It's also not industry standard. The average PBMs out there now really turn around these kinds of exception processes much more quickly then that. And Medicaid generally it's within 24 hours. So we would propose that we have a much quicker time frame.

Also I would just note that these time frames are bifurcated based upon whether the individual has paid or not. That is an unusual thing certainly within the commercial

world. I don't believe that PBMs make a difference now on what kind of appeal rights you get if you pay it out-of-pocket. I am sure they don't even know if you paid out-of-pocket. And it will be challenge for how they will know whether you bothered or not.

But I think the basis of that was that in non-drug appeal rules that there, for Medicare, there is a recognition that if you are appealing for surgery and you haven't had the surgery yet that you need to have that appeal handled more quickly than if you have already paid for it out-of-pocket and you are just trying to settle up the money situation. That that can be a slower time frame.

But with chronic medications where someone comes up every drug for a refill it's a different kind of situation. So that bifurcation even if you can afford to pay for it, the first time around, you might not then be able to afford to pay for it next month.

And to slow the appeal process down so that the first stage is 30 days. And the second stage is 60 days. It means someone is stuck paying out-of-pocket for a very long period of time. And for this low income population that is very onerous.

DR. MURPHY: Can I just add. I am not --.

MS. SCHOFIELD: Yes.

DR. MURPHY: You know the notion, it was

understandable why the notion was, and suggested that there be this longer time point for people that had already paid because then there wouldn't be the urgency.

However, with all lower income populations including SPAP enrollees that means that someone has paid out-of-pocket and may be in danger of having to forego other essential services, rather it be rent payments, heating payments, other utility payments.

And so therefore the necessity in fact of having the elimination of that bifurcation system is probably very worthwhile for CMS to consider.

MS. SCHOFIELD: Thank you. The next point is that the initial denial should be considered a coverage determination. Under the current regulations it's actually quite hard to understand this. But we spoke with folks from CMS and they clarified their position. That when an individual goes to the pharmacy and the pharmacists tries to fill their drug, they submit the electronic claim they get an instant disservice electronic claim denial. That that is not considered a coverage determination.

Now in any other kind of non-drug benefit under Medicare a claim denial is a coverage determination. In other parts non-drug benefits in Medicare if you are asking for prior authorization for example you are requesting a coverage determination because you don't know yet whether you

will be covered.

What is being proposed in this regulation is that that initial claim denial would not be a coverage determination. That after you have been told by your pharmacist who has been told by his plan that your drug is not covered because it's not on the formulary, you would have to call or write a letter to your PDP and ask them for a determination.

In other words you have just been told that it's not covered and you have to ask is it covered. And that coverage determination is considered to be equivalent to an exception request.

It really isn't logical from my perspective. And it adds a lengthy extra step in the process compared to how the process works for non-drug claims. Again you would have that 14 to 30 day time frame. And then you would get your coverage determination. And then you could ask for a redetermination.

Our position is that that initial claim should be a coverage determination and that the redetermination, your request for an exception, should be considered the redetermination, which just makes more sense from a gut perspective.

The next one is about appeals rights should reflect the likely duration of use. This comes up both in terms of

that issue of bifurcation. You know people expect to use drugs for months and months. They shouldn't have a different system for appeals just because they have paid. Because they are going to have to pay over and over and over again.

Similarly an individual who pays for a drug cannot seek an expedited review. Well if you are on a drug that if you don't get it every single day you are going to be hospitalized and you have just used your last pill and you go to the pharmacy for a refill and they tell you oh, you can't have it. You need to appeal.

Well, by golly you are going to pay for that out-of-pocket by hook or by crook because you know you are going to be sick. But then you just eliminated your opportunity to seek expedited appeal process, which is very clinically dangerous for these folks.

There is another issue, and I think it belies a failure to recognize that these drugs come up for refill every month. And that just because you paid for it once doesn't mean you are all set and you will never have a problem again. The problem is going to come back.

Similarly, the duration of use comes up in terms of the dollar threshold that you have to meet in order to avail yourself of the higher levels of appeal. In order to appeal to the administrative law judge and above you have to, the amount in controversy has to exceed a threshold that is set

by law every year.

In determining well what is the amount in controversy the folks at CMS tell us that they anticipate that that would be a duration of no more than two months. Again, for an individual who is on a chronic medication that they are going to need for the rest of their life to only look at the cost of that drug for one month or two months really doesn't portray what kind of financial burden that they are facing over the coming years.

So we would again suggest that that threshold be based upon the real duration of likely use of the drug and recognize that there are many refills yet to be purchased.

Let's see, the last one non-formulary drugs approved on appeal should carry the co-pay of the plan's preferred drug. Currently the proposed regulation says that if you appeal a non-formulary drug and your appeal is granted because the PDP recognizes that your drug is medically necessary, that the PDP can apply any co-pay tier that exists in their plan.

Recognizing that the co-pay tiers can be as high as 100 percent, that means that a PDP could say, yes, we think you are right. You medically deserve this medication. You go right ahead and pay for the 100 percent of the cost of this. And it wasn't much of an appeal process if you wound up having to pay 100 percent.

At that point because there is an appeal process for co-pay tiers, that individual could go through the entire appeal process all over again to appeal for a lower co-pay tier even though they have already established that the drug was medically necessary for them, which doesn't seem to make a lot of sense.

Those two cost issues should be put together and I think the easiest way to do that is to say that when you are appealing a non-formulary drug that the co-pay tier of the preferred drug should be the co-pay tier that applies.

In other words when a PDP denies you access to a particular drug it's because they are saying to themselves you don't need drug X because we have drug Y on the formulary. And drug Y is just as good.

Well they know what drug Y is. Whatever the co-pay tier of drug Y is the co-pay tier that should apply if they finally recognize that drug X really is medically necessary for you.

So that was a really long winded, I am sorry. The appeal process is just very, very complicated. And there is more to it then that. But I am not going to go there.

CHAIRPERSON HENNEBERRY: No. I think you did a great job condensing that complicated portion of our report. Any comments from other commission members or questions from the audience about appeals?

MR. O'DELL: Joan, I would just like to add that the commission did discuss the need to try to help avoid inappropriate denials at the pharmacy, meaning disconnects on communication between the PDP and an SPAP that might fall through the cracks of the pharmacy.

For example if a beneficiary has a prescription that is first sent as a claim from a pharmacy to the PDP and for whatever reason that PDP rejects it or denies it, et cetera, it's important that there be a mechanism, you know a system so that that doesn't just stop when it gets back to the pharmacy.

And the recipient may be walking away without appropriate service. That that information needs to get on to the state plan or another plan if that particular patient has secondary coverage.

One so that the plan knows that. And can take that into consideration and possibly consider that as part of the appeal process. Two, it needs to be very clear to the pharmacy themselves what is going on so that the pharmacy can help play a role in making sure that if an appeal is appropriate that that does take place.

But to depend on a very manual process to ensure that that happens in a consistent way may be asking for a lot. So one of the things that we will talk about a little bit later is potentially for a system that will help make

sure that that effective communication all the way between the PDP, the pharmacy, and the SPAPs takes place without fail.

Because what we don't want is for a patient to walk away from the pharmacy not receiving all of the benefits that they are entitled to just as much as we don't want them to walk away with false information that the claim has been denied and that is all that they can do about it.

So that is something that we recognize that there may be an opportunity to make that an automated process.

CHAIRPERSON HENNEBERRY: Any other comments or clarifications, questions from the audience on this one?

MR. COSTER: I would just build on what Dennis said. I don't think there is a practicing pharmacy in America that understands the Medicare appeals process. And based on my limited knowledge of how it works, if there is a denial that occurs at the pharmacy it triggers a series of steps that the beneficiary is legally entitled to which again I can't articulate for you.

But if it's the pharmacist who is responsible for initiating a process that results in a determination or redetermination I don't know that that is a place that we want to get into. Because for example if I hand something back to the patient and say this has been denied. And if I hand them a document that says officially this has been

denied these are your rights, how do we know the patient is going to know what that is or how to use it or what to do with it. Or what legal liability does that transfer to the pharmacist or the chain or the entity he works for because there are some rights that people have regarding this.

So as much as we want to help people get their medications, I think and I am talking for us as an association, we would be concerned about what that means in terms of the pharmacist getting involved in a legal process and whether there is any liability to him or the corporation he works for if it's not done correctly in spite of his best efforts to want to do it that way.

So again this is a process that we are like totally unfamiliar with. And, you know, there are 165,000 practicing pharmacists out there. And making sure each one knows all this stuff is a huge challenge. Because as much as I read this stuff I still don't understand it.

So I just raise it as an issue in terms of where the pharmacist is appropriate involved in all this.

CHAIRPERSON HENNEBERRY: Any response to that?

MS. SCHOFIELD: Yes.

CHAIRPERSON HENNEBERRY: Linda.

MS. SCHOFIELD: I think part of our thinking was the pharmacists in some cases would like to be able to advocate on behalf of their patients. And they do so now

with prior authorization routinely. And I don't know, but I would love to hear from any pharmacist in the group if with certain plans now if you can seek an exception. If a pharmacist can seek. I know with Medicaid pharmacists can seek an exception from the PDL. I am not sure in commercial plans if it always has to be a doctor who seeks it, or a patient, or --.

But I do think there are pharmacists that do play a role in this now. I understand your concerns about legal liability but why would they be any different then prior authorization. Help me understand that.

MR. COSTER: I don't know. Because I don't know the Medicare process that well whether it confers any additional legal rights on patients as opposed to a contrast with a Medicaid or commercial payers do.

I am just saying that if this is something you recommend it may be useful for you to further elaborate on either how they are similar or how they are different from current commercial or Medicaid plans.

I agree with you. Pharmacists every day will call for example a PBM or an insurer if a drug is denied and seek approval to dispense a non-formulary drug. If that is denied are those rights any different under state law than what might be conferred under Medicare? I don't know. That is why. And I can't read the thing anymore to figure it out

because it's just --. So I am just saying --.

MS. SCHOFIELD: Our recommendation would assume that there is no difference in your role as you just described it now from under Medicare. But we can certainly clarify that that shouldn't create a greater legal liability for you if the plan denies it. Or if you are not quite sure how to do it.

MR. CHASE: Linda, I would --. Similar to that I guess we in the state have struggled, I shouldn't even say struggled with, but taken a position that denials in Medicaid and in our prescription drug program are from the state and not from the pharmacy.

MS. SCHOFIELD: Right. Exactly.

MR. CHASE: And so I think that is the differentiation you may be saying. We can always delegate to a pharmacy that they can provide that information. But it is not the provider's responsibility to give the appeal, what we have with the initial start with that are denial determination or reduction notice.

Just for that reason that it's really not, the provider isn't the one making the decision. You put the pharmacist in the position of saying well I have a denial on this but I don't make the decision I just pass on what the computers told me.

So somehow I think it would be good to kind of

clarify how can we make sure that pharmacies can be helpful with the process but not have an obligation to be the appeal location.

CHAIRPERSON HENNEBERRY: We have Jay and then Sybil.

DR. CURRIE: I think one of the things that is coming up later is that we do propose that there has to be some major education of pharmacists as well as other providers and beneficiaries of how to negotiate the system. So I think once we figure out what that is and if we do get some changes in what the appeal rules are we are going to make recommendations that we have to educate these people who are providers to know here is what you need to do. Here is the place where you feel free to stop because your obligation is done, whatever. So that is coming up later.

MS. RICHARD: Just to follow up on Jay's point. We had a lot of discussion around what the denial was. And coming up with the definition for the initial denial. And I think there are a lot of assumptions about what role pharmacies play.

And here again I think it's to our benefit to assume that pharmacies will do whatever it is they need to do to get that patient that prescription before they walk out of the pharmacy.

So in deciding what an initial denial is, I think

we can come back to the point that if a patient is to leave the pharmacy without a prescription because the pharmacist had done everything that they can do including calling in prior authorization and then not having that resolved then that would count as an initial denial. That would in fact warrant an appeal.

And I think at that point similar to what we do in Florida with the Medicaid program if the pharmacist does everything that they can do and they can identify why this patient is walking away with a prescription. And in fact come to some conclusion that it's not the pharmacist's fault, we have already said it's a coverage termination.

Hand that to a patient. Some documentation that says this is why your prescription was denied. You have done everything that you can do. And I don't know that you would be required to do much more as a pharmacist than what you have already done.

CHAIRPERSON HENNEBERRY: And I think in speaking on behalf, if it's the state, it's the person who is living in a state where there is an SPAP, I mean a next step would be give that person SPAP number because they are there to help that client figure that out as was mentioned earlier.

You have a lot of states where that resource would not be there. But in the states where there is an existing SPAP that is willing to work with that client on the appeal

or provide that coverage during that appeal process then they might have another resource. So there clearly, the SPAPs want to work with the pharmacies to make sure they at least have a toll free number to give somebody if not more information.

MS. RICHARD: Or at least know where to point the patient once they leave the pharmacy.

CHAIRPERSON HENNEBERRY: Right.

DR. MURPHY: Because we did discuss at length the whole issue of what information does a beneficiary get at that stage. And it's probably in nobody's interest, including the pharmacist if the beneficiary is denied their drug. Has no idea on what grounds they were denied a drug. Therefore doesn't know which appeal they are supposed to be utilizing. Doesn't know actually where to go.

And the pharmacist also doesn't know where to send the person or how to assist. Then everyone ends up entirely clueless which probably is in nobody's best interest.

And so one of the great, I think, challenges in the whole system is to try to design a system whereby the pharmacist and the beneficiary receive the most practical information possible in the most efficient manner, with the least burden but also the most practical in regards to solving these issues.

CHAIRPERSON HENNEBERRY: Go ahead.

MR. COSTER: I hate to delay this. But I think if you want, the pharmacist wants to help but it's what you give the patient. Like the message coming back is if there are 12 different messages or 12 different reasons for denial, then how is the pharmacist going to provide that to the patient? Is there a standard CMS form where the pharmacist can check one of the boxes? Your drug was denied because a, b, c. Do you do that? Does every plan have a different one? Is there a standard form.

And remember you are talking about pharmacists who are filling hundreds of prescriptions a day. You want to make sure the documentation is correct. We could again, I think, the documentation triggers a series of legal steps which if not correct is not good for the pharmacist or the beneficiary.

So in terms of at the point of service what you recommend think about operationally how the pharmacy works and what you can do to help the pharmacist make it more efficient to give them the documentation.

CHAIRPERSON HENNEBERRY: John, we didn't actually get into details in our report thus far about exactly how the denial notice ought to be delivered.

And I would leave that to the plans, the PDPs, personally to figure out is it more efficient for them to generate a notice out of their claims system when they

generate the denials. Is it something they negotiate contractually with the pharmacists to print off a screen print that they developed jointly.

I mean there are many ways to skin that cat. And I think it would be presumptuous of us to specify one in particular. But that should be left to the PDPs and the pharmacists and CMS to determine a mechanism.

Our point is that for every other kind of denial out there, there is a notice of beneficiary rights. And this kind of denial shouldn't be any different. Sybil.

MS. RICHARD: Linda, we have come to consensus on a lot of issues that we have dealt with here. This is one where I beg to differ with you. I don't think that it would be efficient for the pharmacies for beneficiaries for plans to have a different mechanism every time there is an appeal or a denial at the pharmacy.

I mean I really think that this is something we should consider and recommend to CMS that they come up with some unified or standard mechanism or process to do this. Because you know in different regions different pharmacies are going to have any number of phone numbers that they need to give to beneficiaries.

And to the extent that we have tried to create standard processes, for example using the standard ID card, I think we should stick with those same principles here.

MS. SCHOFIELD: Okay.

CHAIRPERSON HENNEBERRY: Okay. Well we obviously need to have some further discussion on that as a group. So I appreciate those comments. I would like to get through this one next slide before we break for lunch. Because I think we are going to have some comments from people I know have to leave. So, Julie is going to take the lead on this. Beneficiary education.

Beneficiary Education

by Julie A. Naglieri

MS. NAGLIERI: Well, we are obviously very concerned as we have already heard a lot of this morning about beneficiary education. Particularly as it relates to those beneficiaries who also are involved or enrolled in an SPAP.

Our concerns have grown even more through our experiences with the Medicare drug discount card. CMS has certain requirements on plans for providing materials, education materials, to beneficiaries as they enroll in those plans.

And when there is an SPAP, the SPAP is sort of left out of that loop we have found. And we want to avoid that in the future because the information or message that is given to the beneficiaries from the plan presents a very different benefit that they will actually receive when that benefit is

coordinated with the SPAP benefits.

So for example, well let me give you a true example that New Jersey experienced with the Medicare discount card. Plans were required to include in their enrollment package to their beneficiaries a listing of prices of the drugs on their formulary.

And those prices are very different and very scary to those beneficiaries that are also enrolled in an SPAP who would be covering those costs and the beneficiary would only see a small co-payment, if that at all. And so that would tend to scare the beneficiaries away.

We feel it's very important for the SPAP and the plans to coordinate on this beneficiary education to their dual enrollee to get out a clear message. And not to complicate an already difficult communication challenge that we have.

Our recommendation as a result is that CMS should designate SPAPs to be the primary education/outreach agent for Part D with respect to SPAP enrollments. We feel it imperative that the plans, communications to their SPAP enrollees needs to be coordinated with the SPAPs so they can work together to get out a clear as possible, a clear message to their enrollees.

And towards this end CMS needs to permit more flexibility to these plans in developing those outreach

materials.

CHAIRPERSON HENNEBERRY: Okay. Any questions or comments? Anybody, especially any of the state representative want to add anything to that?

MR. CHASE: I would --.

CHAIRPERSON HENNEBERRY: It makes sense to everybody?

MR. CHASE: I would just say to just clarify that point that sort of should designate SPAPs where appropriate because in our state we would use the SHIP for that because they are already our agent that does the work with the SPAP.

So it wouldn't necessarily have to be the SPAP itself. But the point is still the same. That the entity that is doing the same work with the SPAP needs to have that ability to be consistent when Part D comes into place.

CHAIRPERSON HENNEBERRY: Okay. Any other questions or comments?

(No response.)

CHAIRPERSON HENNEBERRY: All right. We are going to break for lunch. The commission members are having lunch in the Judicial Room right across the hall. For the audience we will reconvene at 1:30. So we will be back in this same room and we will see you then. Thank you.

A F T E R N O O N S E S S I O N

1:36 p.m.

CHAIRPERSON HENNEBERRY: We will get started again. Are there any people in the audience who weren't here this morning? Do I need to remind everybody of what process we are following?

(No response.)

CHAIRPERSON HENNEBERRY: Okay. All right. We are on the slide regarding program evaluation and assessment. And Dewey is going to walk us through this.

Program Evaluation and Assessment

by Dewey D. Garner, Ph.D.

DR. GARNER: Thank you Joan. I remember 40 years ago when Medicare and Medicaid were ---. There are a lot of things happened after that first year that we never anticipated. I think now we have probably the largest change in that program in 40 years with an outpatient prescription drug program under Medicare.

And one of the elements that we are looking at is program evaluation and assessment. We are recommending that CMS should embark upon an assessment of the implementation of a new program such that changes can be monitored and deficiencies can be readily identified and corrected.

The program objective is to assist the success of the implementation of the coordination of Medicare Part D and

the State Pharmaceutical Assistance Programs. Evaluation of Part D should include evaluation of the impact on State Pharmaceutical Assistance Programs and their beneficiaries in the area of accessibility, utilization, claim denials, and satisfaction.

To accomplish the program objectives system measures should be obtained including a baseline measurement before implementation for involved SPAPs, pharmacists and patients.

Measures on items such as satisfaction should be conducted at baseline followed by quarterly system measures. All of these measures should be compared with the previous results as well as baseline measures to identify both positive and negative changes in satisfaction and other measures.

While the satisfaction measures will assist perceptions of the system implementation the system metrics will be used to monitor additional changes in the State Pharmaceutical Assistance Programs.

For example the number of patients enrolled, patient demographics, total expenditures, expenditures per patient, number of failed transactions per month and changes in the prescription mix of the formulary or non-formulary prescript -- and non-formulary prescriptions.

These metrics should also be broken down by

prescription drug plans so that system problems can be identified separate from specific prescription drug plan challenges.

Since the monitoring will focus on changes in the metrics it is difficult to over emphasize the importance of baseline measures before program implementation.

CHAIRPERSON HENNEBERRY: Okay. Thank you. Any additions or comments from commission members? Any questions from the audience about our recommendations around program evaluations and assessments?

MS. FOX: Hi. Since I come from a research community I just think this is a really important component to have in here. I guess my only question is that it seems to not address, and maybe you are going to have a subsequent slide on this, on making the data available for others in the research community to do evaluations.

Not necessarily relying on sort of aggregate measures as done by CMS to be sure that the information that is being basically housed in the PDPs related to drug use and will be available for public health services research community to do their own evaluations. And I would just highly recommend that.

CHAIRPERSON HENNEBERRY: Thanks Kimberly. I know we discussed this. And it may be in the language that surrounds this recommendation. But we will go back and look

at that because I know we have talked about that.

DR. GARNER: Yes. I believe going back to our July meeting I think the person from CMS we talked a little bit about the data they may be collecting and what may be available. We really didn't get into the specifics of what data to collect. We looked at it really maybe as that being outside of our scope of work to a degree. But certainly as a researcher I echo your sentiment.

CHAIRPERSON HENNEBERRY: Any other questions or comments?

(No response.)

CHAIRPERSON HENNEBERRY: Okay. Our next slide is on program redesign and coordination. Bob, I think you are doing this one.

Program Redesign and Part D Coordination

by Robert P. Power, M.B.A., C.E.B.S.

MR. POWER: Right. I had the pleasure of talking through some complex points this morning. And this is just a repeat of that. These two are also complex and let me set the context. I will just try to blow through them quickly and then if anyone has questions we can try to respond to them.

The context here is that some SPAPs may decide to simplify their involvement with the pharmaceutical benefit by paying premiums rather than by paying claims. So that is the

key difference. Some may decide to pay premiums rather than claims. And when they pay premiums we anticipated some rocks that they could get hung up on and we are trying to clear those obstacles away.

The first dot point is that CMS should clarify that assistance, that programs can, I am sorry, that SPAPs can supply assistance to consumers for premiums that are beyond just the standard benefit package. If the SPAP were to decide to buy a richer package from a PDP that we need clarity that that is okay with CMS.

The second dot point is that CMS should clarify that cost sharing, those paid for through a premium should count for TrOOP. And you probably all remember that TrOOP stands for true out-of-pocket costs and it's making your way through the donut hole to catastrophic coverage and so forth.

And it's clear in the NPRM and in statute that SPAP claim payments should count toward TrOOP. But when a SPAP buys by paying a premium to a PDP it buys the same protection then what needs to be clear is that those co-payments a person would otherwise would have paid would count toward that person's TrOOP.

The third point is again I alluded this morning to the different groups of low income subsidy folks. Group one, two, three which was the preambles way of describing the various levels of assistance to low income people.

What we are saying here is that CMS should establish a standard markup on the bid that the PDP is otherwise making. And therefore if the SPAP were to decide to buy into group two and they otherwise would be a group four, there would be a marginal price to get them from group two to group four, if that makes sense.

And then finally the last bullet point about customized supplemental coverage is, that doesn't say much yet. But what we mean is that SPAPs, it needs to be clear that SPAPs can arrange for customized benefit packages, not just simply buying the standard ones that are described by the proposed regulation.

So sorry it's so obtuse, but this is about, the essence of it is about those situations where the SPAP wants to pay premiums rather than claims to obtain coverage.

CHAIRPERSON HENNEBERRY: It also goes to one of our early principles about giving SPAPs and states the flexibility to wrap around and design their programs in the future to meet both the needs of their beneficiaries and whatever is going on in the markets. Any other comments from commission members on this? Linda.

MS. SCHOFIELD: I would just clarify in case that wasn't clear that in some cases the states they want to get out of the business of actually administering the claim processing and all that sort of thing. And pay a PDP to do

all of that for them to cover the co-pays, to cover the non-formulary drugs.

One of our concerns that led to this recommendation was that there, you know, the PDPs at this point could charge anything they wanted for that service. So what our recommendation gets to is to establish in essence a federal premium which is equivalent to what the feds will be paying the PDPs for those kind of wrap around benefits.

MR. POWER: And she is speaking to the third bullet.

MS. SCHOFIELD: Right. That would make it easier. Again going to the principle of trying to make things simple would make it easier for states to actually buy the service from a PDP rather than administering it themselves if they so choose.

CHAIRPERSON HENNEBERRY: Other comments from commission members? Any questions from the audience on this?

(No response.)

CHAIRPERSON HENNEBERRY: No. Okay. Then we are going to move into the recommendations that came out of our third work group, coordination of benefits. And I am going to turn it over to Julie.

Work Group Three - Claims/Payer

Centralized Data System

by Julie A. Naglieri

MS. NAGLIERI: Thank you. First I would also like to acknowledge the members of this work group. They worked hard on the coordination of benefits aspects. That would be Dennis, Dewey, Jim, who is not here right now, Marty and Jay. And also acknowledge Karen Greenrose who is very much involved in organizing us and keeping us on task. And that was much appreciated. A very committed and dedicated group. And it was a lot of fun with the nuts and bolts here.

CHAIRPERSON HENNEBERRY: Julie, we are getting some noise from the next meeting. Can you pull the mic up.

MS. NAGLIERI: Okay.

CHAIRPERSON HENNEBERRY: Thanks.

MS. NAGLIERI: As SPAPs consider supplementing the benefits that are being offered by the Medicare drug plans, Medicare Part D plans, a major concern is how those benefits will be coordinated at the point of sale.

And our objection is on behalf of the SPAP enrollees to ensure that their care, their access to their medications are not disrupted at the point of sale. And also to ensure that the responsibility as primary payer and the SPAP are fulfilled so that the SPAP isn't left holding the bag so to speak for those costs that are the responsibility

of a Part D plan.

So those are two major goals in coordinating the benefits that we are looking to achieve. In order to ensure a smooth coordination of benefits between the Medicare plans and the SPAPs that ensures that the beneficiaries receive this immediate and full access to all the benefits that they are entitled to.

It is very much dependent upon an exchange, a very timely exchange of current information between all the parties involved.

The regulations came out with some options that CMS was considering in support of that data exchange process. And we are supportive of one of those options that has CMS responsible for establishing a centralized data system.

Now this data system --. First of all the data that we are looking at here is the plans first they need to know if their members have SPAP coverage or perhaps other coverage that they will need to coordinate benefits at the point of sale.

And also to properly track an account for TrOOP incurred costs towards their out-of-pocket limits. So the plans will need that enrollment, or coverage information on those other payers.

The SPAPs in turn need enrollment information on what Part D plans that their beneficiaries or their enrollees

have, are covered with. So that they can ensure and help to maximize seamless coordination at the pharmacy. And the pharmacies clearly the pharmacies need to know what coverage is their customers have. You know what Part D plan to bill. How to bill. If that person also has SPAP coverage.

Now we often depend on the beneficiary to inform the plan, to inform the SPAPs, to inform the pharmacy of what coverages they have. But our experience as SPAPs have shown that that is not a reliable source of information for varying reasons.

So we are supportive of the centralized data system whereby CMS would be responsible and perhaps contract with an outside entity to collect this information from the various parties in a timely fashion, enrollment coverage information and updates to that information from the SPAPs, from the Part D plans.

And in turn provide that data back to the, share that data with the plan, with the SPAPs and with the pharmacies through some kind of an access mechanisms that pharmacies could use that would be cost beneficial and efficient.

This information --. And actually I would like to get into the next slide too because they sort of go hand in hand before we open it up. And I really would appreciate any feedback on this.

(Slide)

The reason why we would support this centralized data system and I think the discussion in the regulations elaborated on was to avoid the need for the multiple exchanges that would be required between the SPAPs and the multiple plans and visions and all of that.

So a more one stop shopping kind of place for that information to provide. So it would be much more efficient we feel.

Now this, while we would advocate for CMS to be responsible for this repository of enrollment coverage information, we do embrace the approach that CMS put out there as an option in having the plans responsible for tracking TrOOP.

And I understand there is other, there are other approaches that are under discussion in the industry that we might want to talk about further on this. But at this point we are looking at and suggesting that PDPs be responsible for tracking TrOOP.

Because what is very important from the SPAPs' perspective on behalf of their beneficiaries that this TrOOP be tracked real time, immediately. I mean the last thing that we would want is the beneficiary who truly met perhaps with the help of an SPAP their out-of-pocket limit to have to continue to pay for their drugs until their SPAP or until

their other coverage proves to the party plan, through some paper or some other process that is not as timely, that they truly did incur those costs and they should be accounted for towards TrOOP.

So we really feel strongly that it needs to be a real time adjudication effort at the point of sale when the senior is in the pharmacy and those credits appropriately applied towards TrOOP. And we feel that the plan would be able to do that.

Now the plans would know --. It's a little unique situation with the SPAPs because the plans would know from the CMS centralized data base that their members also have SPAP coverage. And so as they adjudicate those claims and well for example the beneficiary is in the donut hole they know that either the beneficiary or the SPAP pays for that coverage.

So there is no need to require that the SPAP go through the added burden, expense, and untimeliness perhaps of providing that information to the plans. The plans would assume that those costs were appropriately incurred and should count as incurred costs towards their TrOOP.

And there would be no need for collecting claim information from the SPAPs to prove this. And it could truly be seamless.

So we are saying let's use the technology that is

out there, the efficiencies, you know. And what the pharmacy industry would be the standards. The industry standards that are out there and established by NCPDP and other standard setting organizations to put it to its full potential at least where SPAP beneficiaries in Part D enrollees are concerned.

I understand there is also, we might want to talk about this a little bit, Dennis you might want to elaborate on some other thoughts that are out there for enhancing and improving that process even further.

CHAIRPERSON HENNEBERRY: Do you want to add something, go ahead.

MR. O'DELL: Yes. On that point, Julie, you are right. And I think that there is some folks here in the audience that would like to give us some additional details as far as being to able to just kind of graphically see and visualize what the process that is being proposed as an enhancement to the existing recommendations that we talked about.

And I think that by considering that of having a system approach rather than relying on the thoughts, actions of the pharmacy to make sure that coordination take place between the PDP and the SPAPs or other plans is one of the most important features of that recommendation.

And I think it will also be one of the most

important measures that the beneficiaries will have when they walk into a pharmacy and either have a good experience with the process or they walk away frustrated thinking that maybe the flow of information between the pharmacy and the PDP and then back to the pharmacy, and then the pharmacy having to know through some kind of a method that is not clear at this point that oh, by the way, there is a SPAP involved or some other plan that may have something to contribute on this prescription as far as the benefit is concerned.

But to take out a lot of the potential for confusion, for things falling through the cracks at that point. And to utilize the information that would be housed in that status system that you referred to in a way that would allow that claim not to have to go back and forth between the pharmacy multiple times to multiple plans.

And if that is something that the process is and that the industry can support along the NCPDP standards is something that we should consider recommending. So I don't know if this is the appropriate point to talk about that. But maybe it would be if that is okay.

CHAIRPERSON HENNEBERRY: Sure. We can take comments now for the two slides, the centralized data system and TrOOP tracking.

MR. BOSOWITZ: Good afternoon. My name is Roy Bosowitz. I am a pharmacist attorney with the National

Association of Chain Drug Stores, NACDS. And I have with me today John Claimant who is also a pharmacist with Eldersons which is one of our chain members within NACDS. And John at this moment is handing out a very brief description of NACDS' single point of contact systems. We refer to it as SPOCs because it's a lot easier that way.

And you are going to get actually two handouts. And again they are both very short, concise and to the point. The second one I think you will particularly like because it's a diagram of how our single point of contact system works.

I should mention that this idea that NACDS had and our chain members is not all that different from what CMS envisioned with its option two as stated on page 46706 of the NPRM on the Federal Register.

And if I may just read three sentences to give you kind of a background of where CMS is coming from and then briefly tell you how we expanded their idea, their good idea, to include retail pharmacies. And again I am quoting here right from the Federal Register 46706. CMS says,

> "We are considering the following options for operationalizing the data exchange related to Part D coordination of benefit system and TrOOP accounting."

It goes along a little bit and talks about option

one. And then it will go further down the page to option two. And it says under option two,

> "We would procure a TrOOP facilitation contractor to establish a single point of contact between payers, primary, or secondary."

And again to follow up on the final sentence there in that paragraph,

> "This would establish a single point of contact between the Medicare program and employers, State Pharmacy Assistance Programs, as well as primary and secondary payers for enrollment and claims payment information."

And again that was a direct quote from the NPRM.

Now what NACDS and its chain members did was simply to expand CMS', and again you can almost read along with me here on the issue brief, expanding CMS' option two to include pharmacies which would allow a more efficient COB and an accurate calculation of TrOOP that would reduce the Medicare beneficiary's waiting time for prescription medication and supply services.

A little further down the page in the second paragraph, it says,

> "SPOCS would have two major advantages over CMS' proposed option two. Those advantages are that both Medicare recipients and pharmacies would also

enjoy the benefits of a single point of contact system, not only the payers..."

that CMS again referred to in option two. We are simply expanding it. "This increase in functionality maximizes the efficiency and effectiveness of a COB-TrOOP real time system."

This issue brief was presented to CMS by John and myself and also distributed at a CMS COB-TrOOP open forum on September 30th. And I must say it was I think greeted quite positively. We certainly received a lot of questions immediately after that presentation. And John, I know, has received some calls at his office in Chicago.

So there appears again to be quite a bit of interest in this. And again what we have done here is simply expand CMS' own option two to include pharmacies which we feel again would put everybody in the loop and kind of addressing the very things you were talking about in your first two slides.

What I think we should do now, John again here is the expert on the details of this. And by the way he was also the one that penned the very nice diagram that was the second handout. And we appreciate that.

And he will address the pages two and three, some of the specifics that he feels are the most salient points that he would like to bring across. And of course we are

both here for questions as well. Thank you. John.

MR. CLAIMANT: First of all thank you for listening to us. As Roy pointed out on September 30th we stood in front of CMS with this proposal basically just expanding their option two with some added caveats.

And what I would like to do is reference the diagram that I put together which basically points out how pharmacies processes claims in real time fashion. Processing them via the NCPDP --- transaction to a switch or to a processor.

In either case the pharmacy will know if the patient is eligible. They will know co-pay. They will know drug utilization review. They will know formulary information and all that sort. That is pharmacy today as basic as it gets.

Page two is a little more complicated version. And the fact that we have listened to CMS' number two proposal on a central data base. And from our first conference call with them they indicated that that central data base would be accessed using the an X-12 to 70 to 71 transaction.

We had to inform them at that point that nobody in retail pharmacy uses the X-12 to 70 to 71 transaction. And then second of all we have tested this transaction with some of our vendors and they have found it not to work up to this point.

So they are still working on that. And we are still working with CMS to get that to work. But we had to make it known to CMS at that point that if they were expecting that type of system to access their central data base it wasn't happening today. And for pharmacies to access the system to determine order of processing that would be just an inquiry it would not be real time.

In some cases we would not know if the patient maybe changed eligibility in flight between another pharmacy or what their actual TrOOP is. Because if that is updated nightly that TrOOP can change by each prescription that is being processed.

So also in reference to the second slide, after we would determine eligibility by the X-12 transaction w would have to process second, third, and fourth claims depending on how many plans this patient had and then use the multiple insurance cards that the patient has to determine what type of true out-of-pocket costs they are going to have.

This doesn't happen today either. Pharmacies do very little COB. The COB that we do we find very cumbersome in some cases. And that that was part of our concern with slide two.

Now to the point of SPOCs which is slide three, it was pretty much our proposal in developing a single point of contact system which would basically be a switch in all

essence which would house the eligibility, the co-pay of the TrOOP, the COB and the DUR information.

That information would be also be updated on a real time basis from the plans as it is today. We process claims to a lot of Medicaid services such as ACS or EDS or Express Scripts or CareMark that will tell us real time what patients' co-pays are and basically we are handling the same type of transaction in route there.

Basically the SPOC system would be smart enough to know what the patient's TrOOP is at any given point. Part of my concern as a pharmacist and I was listening to some of the conversation was the education piece of the patient, not being able to educate the patient on what their co-pay is at any given time.

I heard comments from CMS that the patient would pay one co-pay and you might find out five or seven days later that that wasn't really the co-pay. The patient might have overpaid. That is really, that is not good for us. The pharmacy would have to go back and try to refund the patient or in some cases even charge them additional money.

So that is a true concern of retail pharmacy and that is the reason why we brought the SPOCs proposal up. There is a lot of other key points to this process. Again, the patient gets their meds quicker. The patients know what their cost share is immediately.

And I think most importantly from a pharmacist's standpoint we know real time drug utilization review, formulary information that is going back from the plan is correct.

And I also heard before about denials and appeals. I was sitting with Roy and actually thinking how the SPOC system could actually generate some type of message to the SPAP telling the SPAP that this drug was denied for whatever reason. And the pharmacy wants to submit an appeal to the SPAP. This could be done real time online by submitting some type of a code through our prior authorization process.

So, again there is a lot of things that the SPOC system could do. We are in the process right now of talking with several switches. One of which was present with us at the September 30th meeting. And they were very intrigued by the idea. So much that a second switch came to us a day later and said why weren't they privy to this information.

So more and more people are coming to us wanting to know more about this type of system and what it can do for retail pharmacy as well as the program of Medicare Part D.

CHAIRPERSON HENNEBERRY: Thank you very much. Do any commission members have questions or comments?

MS. NAGLIERI: Yes.

CHAIRPERSON HENNEBERRY: Julie.

MS. NAGLIERI: I have a question. I also find this

very intriguing. Just a couple of questions. As the diagram is presented is and it may be, it's difficult to put all of the details in a diagram like this.

But I am wondering to what extent would this box system actually conduct DUR or eligibility. I mean how would they know what to do for the various plans as far as DUR for example.

MR. CLAIMANT: Well in actuality what we would be seeing would be some type of response coming back to the pharmacy real time in DUR from a plan or from a sponsor.

MS. NAGLIERI: Okay. So is this essentially working as a switch? A mega-switch ---.

MR. CLAIMANT: We don't want to use the word switch because it's actually a mega-switch. This is something that the switches, in fact in our conversation at my office yesterday with some of our programmers as to what, because right now today we process claims for Blue Cross Blue Shield, Aetna, CareMark and even the Medicaid have different provider IDs that we have to submit on line to the adjudicator to let them know who is sending the claim.

And every one of those are different. Some of them might be our NCPDP member. Some of them might be a Medicaid supplied number. We were thinking yesterday that the SPOC system or the switch which actually NDC does today, they act as a communicator to send the right code to the processor.

So the pharmacy will only have to send one code. And then, you know, the switch would actually do that conversion for us. Same as in a return response on a DUR.

MS. NAGLIERI: All right. So you would, the plan through its processor, through its own individual processor would be doing, subjecting its claim to its own DUR system.

MR. CLAIMANT: Yes.

MS. NAGLIERI: And then that would go through some translation perhaps by the SPOC system.

MR. CLAIMANT: It would either be a translation or would just pass right through like a switch does today.

MS. NAGLIERI: And the biggest part of this other than being the single point of entry and providing, and directing the claim where it needs to go in the order it needs to go --

MR. CLAIMANT: Exactly.

MS. NAGLIERI: -- is critical. But also to keep track of TrOOP.

MR. CLAIMANT: That is our biggest concern. When we actually set and looked at the TrOOP calculations and what we have to tell our patients when they are in the donut, when they are out of the donut. It's just very confusion.

MS. NAGLIERI: So how do you envision CMS getting the cooperation of the other payers whose benefits that they will be providing supplemental coverage for does not get

counted towards TrOOP?

MR. CLAIMANT: Well actually that is a good point because in our discussion in my office yesterday with our IT group we were looking at an indicator that would have to be added to the transaction coming back to the pharmacy to indicate that this was actually counted towards the TrOOP or not counted towards the TrOOP.

It's a claim actually adjudicated to one of the plans or processors that actually didn't have, didn't even touch the TrOOP, if that is what you are talking about.

MS. NAGLIERI: Right.

MR. CLAIMANT: Yes. Actually it would be an indicator coming to the pharmacy. We could essentially reprocess the claim to three different entities of which two only had an affect on the TrOOP and the third one did not. The pharmacy would then be able to tell by that response coming back that we would know exactly who touched the TrOOP and who didn't.

CHAIRPERSON HENNEBERRY: Okay. We have Jim, Linda, and Bob.

MR. CHASE: I just have two questions. One is if you could give an example of the DUR type of information. In other words, if I am understanding this, it's something you said is just being passed back and forth so there might be a requirement which we hadn't quite considered around the DUR

information directly.

But I suppose you could have a DUR requirement that is the same for both the SPAP and the PDP. And right now under our idea you would have to essentially pass that to both of them separately.

This would give you an ability to potentially pass that information one time.

MR. CLAIMANT: Right. And we would be able to tell in one transaction response exactly what the DUR, and we might be getting different DUR from one compared to a second. But in that response we can tell exactly what that, you know, who rejected the claim for whatever reason.

MR. CHASE: And how to resolve it. The second question I am curious about is the, who makes this SPOCs and would be there one. Or is there potential to be more than one as long as it has all the capabilities.

MR. CLAIMANT: I will let Roy answer that.

MR. BOSOWITZ: Again what we are doing is basically building on option two. And option two says CMS would procure a TrOOP facilitator contractor to establish a single point of contact between payers. So they have the plan. We are just simply asking them again to expand it to include pharmacies which would solve a whole lot of problems.

But they appear to be the head of the authority right there to procure a TrOOP facilitation contractor to

establish that single point of contact. So it's right there in option two.

CHAIRPERSON HENNEBERRY: Okay. Linda.

MS. SCHOFIELD: So you are just saying you want them to buy your software.

MR. BOSOWITZ: Well, not necessarily. Again I don't know any more of the detail then I basically read you in option two. And that is why I actually read that very sentence.

MS. SCHOFIELD: If they procure it. They could procure it from NACDS is your --.

MR. BOSOWITZ: Well we don't have that software.

CHAIRPERSON HENNEBERRY: No. You are just saying that whatever vendor, if they put an RFP out to hire a vendor to build this system include pharmacies in this.

MR. BOSOWITZ: That is right.

MS. SCHOFIELD: Oh, okay. I was assuming this was an underlying system you use now for postscripts or something.

MR. BOSOWITZ: No, no, no. Nothing like that. What it would probably be or could be certainly is a switch that again is shown very clearly in the diagram. And that is why again I wanted to kind of bring you back to the background. This is really option two expanded to include pharmacies. And that is all we have done.

MS. NAGLIERI: When you say expanded to include pharmacies you mean so that it alleviates some of the burden on pharmacies of guessing who is primary first of all and where to send that first claim. They just send it to this one spot and you guys all know all of those details so they don't have to incur the added multiple transactions.

MR. BOSOWITZ: To tell you the truth we don't know how else it would work except for this model. And of course the bottom line for all of us sitting here today is the Medicare beneficiary.

In other words the Medicare beneficiary is going to present at the pharmacy and we are not going to be able to tell that individual what they owe. They are going to have to come back and make an extra trip. That is not going to set very well I don't think with the folks out there.

And the TrOOP again can be calculated through this SPOCs proposal.

CHAIRPERSON HENNEBERRY: Linda did you have another question?

MS. SCHOFIELD: Nodding of head.

CHAIRPERSON HENNEBERRY: Okay. Bob.

MR. POWER: I am really glad to see this. And this is what I had envisioned all along was possible was this storehouse for TrOOP knowledge that everyone could call upon in real time. I am really excited to see this.

One of the great surprises for me of the commission's work was to find a very high confidence level at CMS that they could pull off this facilitation contractor, albeit at a smaller role then what you are describing by January 1, 2006. It just seemed unbelievable that they were, oh, yes. We can do that.

They are basing those statements upon their experience with Medicare as a secondary payer MSP systems. I still don't quite grasp why that experience they think that it teaches them so much. But would you, someone, speak to your confidence level of being ready on January 2006.

MR. CLAIMANT: Actually that is a very good question because after our meeting with CMS on September 30th I passed out a few of my cards to some of their CMS people, because they were sitting mostly in the audience. And then I had a couple of calls that following Monday, especially from their IT people already asking questions. How can we make this work.

In fact one gentleman of which of which I won't even mention his name says that he was trying to suggest that the 270/271 is not going to work. That the 270/271 is not going to work in retail pharmacy. But he didn't have anything improved.

So he was very glad to see us there. He was very glad to hear us on the phone conferences that we were on with

CMS with NACDS and even NCPDP. I am an NCPDP board member as well. So I was sitting on a couple of phone calls with CMS.

They heard over and over again from me that that doesn't work in retail pharmacy today. And NCPDP made it very well known to CMS that they are willing to work with them if we need to make any changes in the NCPDP file one standard to make it work.

CHAIRPERSON HENNEBERRY: So if the universe agreed that this proposal was the right way, no facetious answers, how do you, what is the time line you need to have this ready, tested, up and running, ready January 2006? When it seems like you would have to hire a contractor pretty darn quick.

MR. CLAIMANT: We have a very aggressive time schedule that Roy put together with NACDS. And we have our folks and a lot of other people looking at the actual claim and what we would like to see come back from the SPOCs. And then we are also working with the switches. The three main switches that have already gotten back to us with what their proposal would be as far as how they would see the system work.

We are going to have that meeting on October 25th between the switches and NACDS. And then the providers. And then what we are going to do is we are going to bring in NCPDP into that picture.

We want to try to get this done and put on the table in front of CMS that says all your work was done. We have gotten the switches together. Now the switches have to go to CMS to say we can do this for you. This is what it is going to cost.

MR. POWER: What do you think your biggest vulnerability is to pulling this off?

MR. CLAIMANT: I can't see any to be honest with you.

MR. BOSOWITZ: No. To address your point and to follow up a little bit on John's comment. We have talked to the three largest switches in the country. And they seem all very anxious to participate in this proposal and to take a look at it.

I put right up front, I said we have to have this done by January 1, 2006. It has to be rolled out ready to go. And they are of course very, very aware of that. These folks are in the switch business, all three of them. They have been doing an awful lot of claims. Probably, what, 80 or 90 percent of all the claims in this country.

So if anybody can pull this off they can. And as John mentioned we have a very, very, very tight time frame to involve these switches. What we have today, as a matter of fact it's due from all of our chain members, we are taking a look at the segment coming back from that switch. And what

our pharmacies would like to see coming back.

In other words would we like to see coming back how much the primary paid, how much the secondary paid, and the update TrOOP all on one claim.

Now we are going to refine that a little bit today. And the comments are going in. And we are going to kind of rewrite some more detail. And that is going to be part of our conversation on the 25th with the switches.

The switches have already been sent copies of our proposals. We have had some conversation. And things seem to be moving right along. I see this rolling out more or less in three phases.

The first phase of course is chain pharmacy. That is what folks that I represent and that is the group that I work with closely. So we had to make sure that we had our act together on this and basically understood what it is we wanted and needed and what the Medicare beneficiary needed.

And then number two to bring in the switches. Get their input. And say okay this is what we think. What do you guys feel that you need? What has to happen here? What would it look like? What would the time frame be?

And number three would be the phase three would be folks like yourselves. The payers and saying all right, this is what we need. And then again you would be interfacing with the switches and with pharmacies.

So we are getting input incrementally all the way down the line to build more detail into this proposal. But I think in the grand scheme of things, in the simplistic diagram, it's the right infrastructure. I think it's the only infrastructure that can possibly do what the goals of the Medicare Part D program are. I don't see it doing it any other way.

CHAIRPERSON HENNEBERRY: Can you tell us again who the three switches are? These are companies?

MR. BOSOWITZ: Yes. They are. NDC, which has already been mentioned. We have ERX. And then WebMD. And again all three of them have been contacted. They are having internal conversations. They have promised to have folks on our call the 25th of this month.

And they will be given all of the information to take a look at internally and we will hopefully have a very productive conference call on the 25th. But we are all inclusive. We want to get the best ideas. And we are being totally open with this. But we need the other folks' input like the switches and like the payers. Yes, sir.

CHAIRPERSON HENNEBERRY: Marc.

MR. RYAN: Well, just underlining. It really means that every SPAP essentially needs to go through this system as well. So you are relying on every SPAP vendor whoever that may be out there if you are wrapping around to buy into

this single point of context system. Otherwise you really can't do the TrOOP. You could have a non-covered drug that still would count toward out-of-pocket expenses or just generally the co-pay issues.

MR. BOSOWITZ: That is correct. And again that is why we are doing it incrementally. Pharmacies getting our act together first. And then putting it out to the switches. And then going to the actual payers out there and saying, okay, this is what we have so far, what more do you guys need. This is what we foresee. And we want to roll it again very sequentially here.

CHAIRPERSON HENNEBERRY: Okay. Marty.

MR. SCHUH: This question is probably premature. But it's worthy of note I think. If I am a potential PDP or MA-PD I would want to know ahead of time what the pricing incrementally is going to cost me for this new switch. And when might that be available. Because the bids as you know are due early next Summer, I think, for PDPs.

So how would that --? There seems to be a time line, maybe a disconnect there if I am reading this --. This is a huge scheme project. And would this be feasible to have some kind of pricing information by the bid date?

MR. BOSOWITZ: Excellent question. As a matter of fact we put the cost question out to the switches already. And we said you guys have to keep an eye on the costs and

come up with an estimate. Again what we are doing is we are really pushing our deadline on our conversation with these folks rolling out this thing incrementally as quickly as we can so we can get that cost information coming back as soon as possible.

I wouldn't imagine, John, I would think it certainly wouldn't be any more expensive then they are working through switches today.

MR. CLAIMANT: Right. Currently --- the switches are doing --- are doing a lot of what we are talking about. (Away from microphone.) And currently today the switches are doing a lot of what we are talking about right here. The only thing is they are not doing the TrOOP calculation. We are not doing the TrOOP calculation.

Or they are not, you know, they may not be communicating back and forth with some of the SPAPs like we are talking about here. So, that is the only thing that we would have to make sure all of the ducks are in row before we actually say this is truly feasible and we really want to do this.

CHAIRPERSON HENNEBERRY: So it's not going to cost the states a whole lot of money you are saying.

MS. NAGLIERI: Well, actually that is sort of an interesting thought. Because the SPAPs probably are working with these switches now.

MR. BOSOWITZ: They are.

MS. NAGLIERI: Because they are the three big switches.

MR. BOSOWITZ: They are.

MS. NAGLIERI: I know we are in New York are. But the pharmacies incur the transmission costs at this point for the switches. And theoretically that is all in our reimbursement to them. And if these are the user fees for coordinating benefits CMS envisions to have to spread among all the payers except for SPAPs. I don't know how that will all play out.

MR. BOSOWITZ: Well, again, just by reading option two it sounds as if we would procure a true facilitation contractor. It sounds like they have in mind the money to get this thing rolling.

MS. NAGLIERI: Well there are provisions for the user fees.

MR. BOSOWITZ: That is a possibility. That is correct. So hopefully again option two they had in mind picking up some expenses there.

CHAIRPERSON HENNEBERRY: All right. We probably need to move along. Go ahead Marty. One more comment.

MR. SCHUH: So would you envision a SPOC system owned by the three switches? Or would this be three SPOCs?

MR. BOSOWITZ: Well that is, good questions. This

is something that we perceived as a possible issue ourselves. And what we did is basically saying look you guys, this is our proposal that we have got developed so far. And we need your input on it. Now however you guys want to work on this, whether you want to do it independently, you want to do it together, that is really up to you. We are not going to get involved in that one.

But it will be interesting how it plays out. Because no one switch is likely to have all the good ideas. And that is why we wanted the input of all of the three major guys and said you have to be on the same conference call together.

And I will tell you, I was not that optimistic that that was ever going to happen. But we made it sound like, you know, this is the way we are going to go. Whoever is going to be on that call we are going to work with you on this proposal. And they all ended up saying yes we are very willing to be on the call.

MR. SCHUH: Well my fear and the fear of CMS and probably Congress too is that this becomes anti-competitive at some point if you have one person in charge of all the information. So how a plan or a state or what have you I am held hostage by what could be an unreasonable fee structure because of market forces.

MR. BOSOWITZ: Right. Now what this is, now,

again, it's a switch. It's a pass through. They are passing through information.

CHAIRPERSON HENNEBERRY: Well, we really do need to move along.

MR. SCHUH: --- freedom.

MR. BOSOWITZ: No. It's not free. That is true.

CHAIRPERSON HENNEBERRY: All right. Thank you both for being here. It was very helpful, very informative.

MR. BOSOWITZ: Thank you.

CHAIRPERSON HENNEBERRY: I think our next, did we have any other comments from the audience or questions about this or TrOOP tracking?

(No response.)

CHAIRPERSON HENNEBERRY: We really should have gotten those visuals with the TrOOP trackers and the SPOCs. We just could have had a lot of fun with this. But oh, well.

(Laughter.)

CHAIRPERSON HENNEBERRY: Julie, I think our next recommendation is right in line with what we were just talking about.

Technical Advisory Committee

by Julie A. Naglieri

MS. NAGLIERI: We are suggesting that a technical advisory committee be established by CMS to provide input to some of these very technical issues. And during

implementation and post-implementation as we all know going through implementations of this sort there are unforeseen issues or technical problems that come up. Or also opportunities such as that you just presented here.

And so we would be recommending such a group that would represent the various stakeholders involved in this to provide recommendations and develop requirements to move forward and enhance the system. The date infrastructure that we are speaking of towards meeting our collective goals.

CHAIRPERSON HENNEBERRY: Any reactions to that?

(No response.)

CHAIRPERSON HENNEBERRY: Does it make sense to people?

(No response.)

CHAIRPERSON HENNEBERRY: Okay. That is good. We want our ideas to be good ones. Any other questions or comments about that?

(No response.)

CHAIRPERSON HENNEBERRY: All right. And Julie you have the next one too. PDP sponsors.

PDP Sponsor Requirement

by Julie A. Naglieri

MS. NAGLIERI: Okay. Well, while we acknowledge that the statute and the regulations appear to require that plans, do require, specifically require that Part D plans

comply with CMS guidelines and requirements for coordination of benefits with SPAPs we think it worth to expressly state that plans should be required to coordinate benefits with SPAPs. And it may be a philosophical thing.

But one where as SPAPs are very sensitive to. Because we have had some experience in the past of getting all of the plans in a cooperative mode and coordinating benefits with us and it hasn't been a pleasant experience or successful experience. And we just want to make it, state that very clear.

Further we embrace CMS establishing as they plan on clear guidelines and requirements to support this coordination and provide seamless coverage, benefits I should say, coordination of benefits at the pharmacy to SPAP and Part D enrollees.

Now our next few slides are offering some details that we would like to see included in those requirements. And clearly they do not, they might be a little step back from what we just saw here in the presentation on the TrOOP tracking and whatnot.

But short of implementation of such approach which would involve the switches we have some ideas to sort of make sure and strengthen that coordination between the plans and the pharmacy and the SPAP occur. And I would just like to run through them.

(Slide)

First most payers have ID cards that they issue to beneficiaries. And beneficiaries are expected to present that card to the pharmacy so the pharmacy knows who the payer is and perhaps how to bill the payer.

We understand that many of the beneficiaries, they don't always present the card. They don't always present all cards that they have that apply when there are multiple plans. And this whole multiple coverage and certainly as move forward is becoming a bigger issue then it had been in the past.

We also recognize that the payers use different cards or, of course they use different cards but the cards have different information on them. And so there is not a good standard that is followed. And there is some evidence, I think it's 25 states that have passed legislation to require that standard ID cards be used, or ID cards, standardized ID cards be used by the payers in those states to facilitate the communication, clear communication to the pharmacy on other coverage.

We are supportive of that. We acknowledge that NCPDP has an ID card standard that we are endorsing and recommending that CMS endorse and require all payers to comply with. And that will help facilitate that communication between the plans and the pharmacies on who the

payer is and some basic building requirements as well.

We also are supportive of a universal payer ID. The NCPDP telecommunications standards provide for a payer identification number that is envisioned, as we understand it, to be universal. Much like the pharmacy might think it's now an NCPDP pharmacy number is used.

So that when an SPAP is communicating to the pharmacy and the plan is communicating to the pharmacy they can reference that same payer ID number and the pharmacy will know what payer they are talking about instead of depending on trying to cross reference a proprietary payer listings and what not. So we encourage CMS to get that universal payer ID up and going as we understand HIPPA required it to be.

And the next guideline we are suggesting and supporting and I am wondering if this actually goes back to the recommendation that we just heard before. The thought we just heard before. And that is a payer to payer transmissions. I mean I think that basically is what we are looking at here.

And I had hoped with the implementation of NCPDP version 5.1 that is what the enhanced coordination of benefits that we were going to be seeing so that the pharmacy submits one claim to the primary payer. And that primary payer then sends it on its way to the secondary and so forth. And then one response comes back to the pharmacy. I mean it

sounds like this is very similar.

So there may be some refinements there. But this commission was recommending the endorsement and sooner than later implementation of this payer to payer transmission.

Also unfortunately I hate to even mention this but the retroactive payment process I think, or recovery process is one that still needs to be in place sort of a catchall or whatever.

Because there are always instances where it just doesn't happen at the point of sale. The right information isn't there. Or there may be some retroactive processing center incur that, find that. An SPAP may have --. Well, and also perhaps the result of appeals that happen after the point of sale.

That finds that the SPAP perhaps paid on behalf, for a drug on behalf of a beneficiary that should have been paid in the first instance by another plan. And so we would like CMS to include in their guidelines a provision for a retroactive recovery process and the cooperation of the payers to comply with that to ensure that they take the responsibility for payment as they are being paid to do.

We also encourage CMS to include in their guidelines a requirement that the, and this may all go out the window and not be needed if we have a better process. But, we would like Part D plans too because they will know

from the central data base system, they will know that their member has SPAP coverage.

And we would like that plan to be required to on their claim response to the pharmacy inform the pharmacy of that secondary coverage so that the pharmacy will then get that information directly from that response. And then know to bill the SPAP in their area.

And we don't, we really don't feel that SPAPs should be required to pay the Part D plans for users fees and coordinating benefits. And we are quick to point out that SPAPs do a service in some ways, in some instances, in some states. And helping to increase the attractiveness of the package that that Part D plan is offering.

And so the benefit of coordinating benefits is joint. We don't think that Part D plans should be able to impose user fees on SPAPs. And we don't think SPAPs should be able to do the opposite.

Now there will be cases where there may be some outside negotiations for special processing and whatnot beyond the routine coordination of benefits. But, for the coordination of benefits that are defined and required by law we do not think that SPAPs should pay user fees.

CHAIRPERSON HENNEBERRY: Okay. Thank you, Julie. Any clarifications or additional comments from commission members and questions from the audience?

MS. FOX: I just had one more of a clarification. And it actually applies through out. And this is probably the case. But you are requiring all these things for both the MA-PDs and PDPs, right? Because I just noticed that a lot of it doesn't specify that and clearly you would want to specify that.

CHAIRPERSON HENNEBERRY: I am going to let our expert on this clarify this for us.

MR. POWER: The MA-PDs are involved. But remember what is envisioned is that we will have a preferred PDP. And that members who are not in MA organizations will most of them will end up in one or two or some small number. And so the SPAP will be dealing with fewer transactions for others.

People will, 12 people will opt out to that PDP and nine to this one and so forth. But the numbers should be very small. In the MA world, what we are talking about is not coordination of benefits routine, but rather the giving of an actuarial equivalent of the benefit that is enjoyed by people in the preferred PDP. And that will take a variety of different forms so long as it is actuarially equivalent.

And so the assumption is that there would not be the same sort of incredibly complex connection between the SPAP and the PDP that there is in the world of the preferred PDP.

MS. FOX: But then how will the SPAP know what it

is paying for within the MA-PD if they don't get that information back from them?

MR. POWER: Well many times what they are going to do is be paying them a premium, you see.

MS. NAGLIERI: I am sorry, Bob. I am a little confused about that. I mean right now with the Medicare plus choice plans SPAPs they are the ones that largely coordinate benefits with. And I expect that some SPAPs will not be paying the premium. And will be supplementing that coverage.

MR. POWER: Well, what we have designed here, the big picture of what the commission has talked about is a permissive system in which the arrangement between SPAP and the MA-PD is whatever they decide mutually they want it to be. And if that is coordination with all of its complexities that is fine. If it is paying a premium that is fine too.

MS. NAGLIERI: So would not these suggestions apply to the MA-PDs where states are wrapping around those kinds of things?

MR. POWER: I think I missed a couple of key words there. Could you say it again?

MS. NAGLIERI: Would not these recommendations apply to the situation where the SPAP enrollees are also in a MA-PD when we are --.

MR. POWER: When the mutually agreed arrangement is coordination, yes, they would apply. Is what I envision.

CHAIRPERSON HENNEBERRY: You mean where we in general, where we say PDP sponsor in any of our recommendations we are talking about PDPs and MA-PDs wherever it appropriately applies.

MS. NAGLIERI: Right.

CHAIRPERSON HENNEBERRY: Marc.

MR. RYAN: I guess my only comment would be I like the idea that you have a central clearing house. I share some of Marty's concerns about the sort of one guy has the control of your destiny forever and down the road you are paying the price for it.

But I also think if this, if we are going to endorse this I think it almost has to be, if you are going to go down this road it almost has to be everybody has to be in the system. I don't know that we can have a situation where MA-PDs could opt out.

And PDPs would have to do it or they could opt out as well. Because in essence what you are asking states to do then is to spend dollars which right not are not being reimbursed at all in this system to integrate in with the SPOC.

And then you theoretically also might have to wrap around even in a small way MA-PDs or other PDPs. So it could actually complicate states technology efforts I think.

MR. POWER: Are you worried that the MA-PDs would

not participate in the TrOOP tracking? Is that what you are worried about?

MR. RYAN: Well, what I guess what I am worried about is what I thought I heard you say, Bob, was if the, if we are not going to pay a actuarially equivalent premium to whatever wrap around type we are doing with other plans what would that relationship be with the MA-PD and would you guys be using the SPOC system as well in that case or not?

MR. POWER: Presumably so. Yes.

MR. RYAN: Okay. Well that clears it up a bit. I just, now I am hearing a very efficient system potentially having a whole lot of tentacles to it.

MS. NAGLIERI: Yes. I was a little confused too. Because I envision, I mean Kim asked the question. I envisioned the MA-PDs and the PDPs to be one and the same for purposes of our discussion.

MR. POWER: They can be. But the point of many of our discussions has been if there would be permitted for an actuarial equivalence to be paid. That is the key concept. And that can take the form of a premium in return for a promise to pay claims in a way that is actuarially equivalent to what would have been achieved through the SPAPs preferred arrangement. Okay? So it could be either.

And I have been envisioning that the MA-PDs would participate in TrOOP tracking to the extent that every once

in a blue moon you are going to have somebody, the most, actually about the only reason that somebody is going to change out of an MA-PD in mid-year is if they move from Minnesota to Florida.

And when they take their TrOOP into their new situation yes, the MA-PDs have to participate in the system to let the next carrier know where the TrOOP is at when they move. But this is very small volumes.

CHAIRPERSON HENNEBERRY: Okay. Anything else on this?

(No response.)

CHAIRPERSON HENNEBERRY: All right. Our next slide has to do with education. We talked about this a few times earlier today. But Jay you are going to do this one.

Education of Beneficiaries, Prescribers and Pharmacies

by Jay D. Currie, Pharm.D.

DR. CURRIE: Yes. As you can see we envision that this could be a pretty complicated system. And our goal, one of our overriding goals is to have this be on the surface a fairly simple process for the beneficiaries to negotiate. And if that is to happen everybody needs to know what their role is. How to make the system work for them.

So we feel that this is something that we cannot just hope works out. There needs to be a concerted effort up front to make sure that we have all of the parties educated

as to what their role is and how to negotiate the system.

So we feel that CMS should fund, develop, and deliver education programs for the facility understanding the program and operation of the program to both beneficiaries, and this is beyond information to help them enroll. This is now you are enrolled how do you navigate this. What are your options in getting the benefit. Prescribers and pharmacists.

And some of the very simple things is just how can you determine what somebody's coverage is. What do you do when you get this type of denial? Where are the sources of information to either have the patient or the pharmacist go to try to resolve the denial of claims.

Basic operational type of education as to how to make the system work for all parties. How to negotiate the formularies, et cetera.

And also then that CMS should again in this purpose of trying to improve coordination of benefits should be facilitating coordination among all of the stakeholders whether that is the PDPs or the providers or the beneficiaries to make sure there is an ongoing discussion to make sure we are not having problems continue that aren't being addressed.

CHAIRPERSON HENNEBERRY: Any other comments or additional information from commission members, questions from the audience?

MR. COSTER: I will just ask if what you mean is that CMS should fund these directly in addition to what they are giving states already through the grants? Are you talking about CMS allowing states to use that money? Because I don't know whether there are any strings attached to that money that the states or getting, or if you had any conversations with them about that.

So I would, I guess I would maybe clarify in your report and you may be doing that whether that means CMS should allow states to use grant money given to them for 2005 and 6 for that purpose. Or this should be in addition to because one concern would be CMS does something and the states do something. And then you have all this, too much information out there. So I think maybe fund and coordinate the educational programs. So it's just for scratch.

CHAIRPERSON HENNEBERRY: Thank you.

DR. CURRIE: I think our previous discussions were to have this be separate money from that that has been dedicated to sort of marketing and enrollment sort of education of beneficiaries. That this would not be out of that set of money. But I can't, we also haven't talked to CMS to see what it feels about that. But we do think this is a very important part of making this benefit actually work for the beneficiaries.

If the pharmacist just goes up and the claim didn't

go through, I guess you are out of luck. That is not going to be the purpose of it. They need to know what to do at that point. The beneficiary needs to know what to do if that happens. Prescribers need to know how to navigate the formulary issues and decisions on what drugs to pick just to make things work.

So I think some of it is going to depend on how complex the system really ends up being. If we have a central data base and we have SPOCs it's going to be a lot simpler. You can negotiate that. Then if we have a system where what do you do when the primary PDP doesn't pay but it's going to go to the SPAP. Or what happens when the primary pays but then for some reason the SPAP has decided its formularies isn't going to take care of the drug.

Where it all can break and how to deal with those areas where it does get broken is what we are concerned everybody knows how to do up front. Rather than solve it and figure it out as we go.

CHAIRPERSON HENNEBERRY: Yes.

MR. CLAIMANT: Actually that was brought up at our CMS meeting. I think it was George Mills that actually brought it up that education of a pharmacist was key to making the program work.

And it sounded to me like there was going to be some huge effort there to make that happen. Because I have

to tell you from our stores' standpoint making the discount program work was very difficult. We had a lot of education problems. A lot of patients that really didn't know that much about the program.

And our fear is that the same thing is going to happen with the Medicare Part D program unless we really truly get that type of help from CMS.

DR. CURRIE: Thank you.

CHAIRPERSON HENNEBERRY: Jim.

MR. CHASE: Just to comment on that. I think it is helpful to hear that we might need to be more explicit with how, what this recommendation means. Just what exactly is CMS supposed to do.

Especially around the point of it's just, yes, these need to be addressed and we will deal with that by giving a grant to each state which I think maybe envisioned now we might miss that. At least in our state I think we would say we would want that grant for our senior linkage line which does the education for the recipients out there.

And I think we are implying by this that CMS should have more of a plan with this. That there would be money earmarked towards particular audiences. And I think we just may need to be more specific about that if the committee agrees in our further deliberation.

DR. MURPHY: Yes. I don't think in our

deliberations we really ever were trying to imply that this was designating the states dollars for this particular use. We were really implying that in addition to that. Because it's really not all that much money that the states are getting in regards to their beneficiary education. And they will be easily, quickly used up. But this is really an additional.

CHAIRPERSON HENNEBERRY: Could somebody, one of the state people, those of you who received some of the grant funds is it your understanding that if you as a state decided that you wanted to use some of those grant funds to target education at groups other than beneficiaries are you allowed to do so?

DR. REINHARD: Yes. It's very broad. CMS has, that's probably the broadest pot of money I have ever gotten. It says, you know, go forth and transition.

DR. MURPHY: Although it's broad, it's small.

MS. NAGLIERI: I would like to add there is a little discomfort because it is broad. We want to feel comfortable that we are using it as intended. And I also want to make the point that those monies seem to have a focus of educating the beneficiaries. And this was raised in the context of this whole complicated coordination of benefits at the pharmacy and the real need to communicate between the beneficiaries, the prescribers, the pharmacies on how to

effectively use those benefits. And this is sort of an ongoing education quite honestly as opposed to just the initial get up transition of the Part D benefit.

And I think we want to distinguish and point out the need for such education among all payers, players I should say in effectuating those benefits and coordination.

CHAIRPERSON HENNEBERRY: Sybil and then Marc.

MS. RICHARD: And we talked about the lessons learned from the discount card. And I think one of the things we learned was that again relying on the assumptions of what we know the pharmacies to do, they became the default educators. And we did not want that to happen.

We saw a better place for CMS to plan this out then to just let the chips fall where they may and let the education go as it would. So it was important for us to at least identify opportunities for education for providers and other groups.

CHAIRPERSON HENNEBERRY: Marc.

MR. RYAN: I think the other reason this is additional dollars is because not all states receive those grants. I mean there were SPAP, what we would view as pharmacy states that didn't qualify as SPAP states under the law. And they were not part of the 62 million or what it was.

So, you are going to have education issues in those

states even if they are just discount card states, things of that nature. So it really is going to need to be a different pot of money, a different program almost.

I would say though that you know those are sort of free wielding grants. The third qualification is facilitation and things of that nature. And I suppose you could even use those dollars on administrative purposes. And we are trying to look at that.

But I think we also have to be cognizant of the fact is that if CMS will at the beginning of next year begin the process of doing an education program we almost might want to take our dollars and make sure we coordinate with the national one. Because that could even create even more confusion.

DR. REINHARD: I do want to add that our subcommittee had a meeting with Michael McMullan who is obviously very involved in leading an effort at CMS along with Gail Arden and others on educating beneficiaries across all the SPAPs and Medicare Part D and Medicare more generally. And I think that that is going to be very important that we coordinate or keep informed about that education message and methodology.

Because our biggest concern is that messages will come out from CMS that are very broad and are not tailored to the State Pharmaceutical Assistance issues which then gets to

the pharmacist as well. Trying to just tailoring that message is going to be a huge issue for us, I think.

CHAIRPERSON HENNEBERRY: And if you remember in an earlier recommendation where the states asked for flexibility to be in control of, when you are an SPAP state that is going to coordinate benefits that you have sort of the final say if you will on the education materials and controlling both the quantity and the quality. That sometimes saying more than the beneficiaries in your state need to know is just going to confuse them. Any other comments on this?

(No response.)

CHAIRPERSON HENNEBERRY: All right. I am going to suggest since our snacks are here that we just take a get up and get a snack break and try not to leave the room. And just give everybody a few minutes to grab something to drink and a pretzel, and crackerjacks or whatever. Then we will start again right at 3:00 o'clock. And then I think we will be able to probably finish. We have two more slides and these are miscellaneous recommendations and unresolved issues for the commission.

(Whereupon, a brief recess was taken.)

CHAIRPERSON HENNEBERRY: I have two more slides.

by Joan F. Henneberry, Chairperson

CHAIRPERSON HENNEBERRY: This next slide is a group of miscellaneous recommendations that some of which we need to flush out a little bit more when we write our report. But they just didn't seem to fall into any other category on previous slides, the bullets didn't. And that may change as we write the report. But I will take a stab at these and then invite the other commission members to add anything they would like.

We are recommending that CMS form an SPAP specific advisory committee. And this is different than that technical advisory committee that we recommended a few slides ago. It's just what it sounds like. It is really a recommendation to deal with the management information systems kinds of issues.

This is really to have an ongoing, the commission work ends January 1st when we turn in our report. And we felt that there needs to be a vehicle for ongoing communication and relationships between representatives of State Pharmaceutical Assistance Programs especially through the early implementation of Part D.

And there needs to be a formal vehicle for that to happen and regular communication between the SPAPs and CMS. Not that they have never talked to each other prior to Part D, but there is no required or natural relationship

between SPAPs and CMS. The way there is between Medicaid directors for instance or Medicaid waiver programs.

And in fact there is a technical advisory committee, I think. There is a committee already of Medicaid directors who have been meeting with CMS to talk about Part Ds. So the SPAPs are asking for some similar structure and ongoing relationship. Anybody want to add anything to that?

DR. REINHARD: Joan.

CHAIRPERSON HENNEBERRY: Susan.

DR. REINHARD: Just that at our meeting last week I know that CMS had suggested or I heard that CMS is suggesting that a particular Medicaid director might, who also has a State Pharmaceutical Assistance Program under her domain might serve that role.

But I think this commission felt that was not enough. First of all to have one person and secondly to try to keep it all together in one person was asking a lot of that one person to keep raising all of these issues. So I just wanted to make sure that was on the table.

CHAIRPERSON HENNEBERRY: The second is that CMS should not allow involuntary disenrollment from PDP plans, PDP sponsor plans for disruptive behavior on the part of the beneficiary. And evidently there are provisions that allow for disenrollment for a number of reasons. But in this

particular case we don't think that that in and of itself should be reason for a plan to be able to disenroll someone. And if that policy cannot be changed then the individual needs to be able to appeal that disenrollment decision from the plan for engaging in disruptive behavior.

I am not sure what the definition of disruptive behavior is. But --. And if anybody wants to clarify that a little bit feel free.

(No response.)

CHAIRPERSON HENNEBERRY: Any other comments about that or any questions from the audience about this?

(No response.)

CHAIRPERSON HENNEBERRY: Okay. "Institutionalized dual eligible individuals". And that is in quotes because that is the way it shows up. But institutionalized dual individuals for purposes of the co-pay relief should be broadly defined.

And this has to do with exempting certain populations, institutionalized populations from co-pays. And we are just suggesting that the definition of who those individuals are needs to be broader, as broad as possible. Marc was this one of yours? Did you want to comment on this a little bit?

MR. RYAN: Sure. As everyone is aware it's clear, well this really ties in the act to the Social Security Act

in that definition. And essentially right now from our reading of it, and we might need more guidance on it, it basically indicates that obviously individuals that are in skilled nursing facilities and similar institutions.

And we also believe intermediate care facilities for the mentally retarded would be within this definition of institutionalized duals. You know I believe we are right on the ICF/MR residents. But it's not absolutely certain.

The other individuals that we are particularly concerned about would be individuals that have very low personal needs allowances. Like a 1915(c) waiver MR group home. As well as those who are in boarding homes.

For example residential care communities. And things of that nature and other therapeutic treatment centers that also have very limited personal needs allowances and clearly cannot afford that cost share. It's just as simple as that.

You know if the understanding is that the reason that an institutionalized individual in a skilled nursing facility might have a personal needs allowance of anywhere from $50 to $80 in a given state cannot afford that cost share.

It clearly would stand to reason that individuals who have up to $130 personal needs allowance per month probably could not afford that cost share if they are also

very medically fragile.

This ties a little bit into what we talked about earlier. That is sort of the cost share argument. The formulary argument under the special needs status which these folks would fall clearly is a concern. Because that could bankrupt a person each month as well.

So we almost think in a general sense, although we understand you can't totally outright say no formularies for any special needs populations. In a general sense we think that both on formularies and on cost sharing that those special needs populations or institutionalized populations really need to be treated differently than the base of the law to a great degree at the very least.

CHAIRPERSON HENNEBERRY: Okay. Any questions about that? Or comments from other commission members?

(No response.)

CHAIRPERSON HENNEBERRY: Okay. And then the final bullet on this slide remembering that our recommendations are, the audience for our recommendations in addition to the administration and Congress are other State Pharmaceutical Assistance Programs who have not been part of this process or who even if there were turnover for instance and people wanted to look at recommendations later on to think about their program.

So one of the recommendations is to themselves and

their colleagues, State Pharmaceutical Assistance Programs, really need to if they haven't already developed a relationship with their local Social Security Administration Office.

But to say in constant communication with them to better coordinate all of the things we have talked about. Outreach, marketing, education, systems issues, changes in policy and program. And to just maintain that relationship and keep the lines of communication open. Any questions about that?

(No response.)

Unresolved Issues

by Joan F. Henneberry, Chairperson

CHAIRPERSON HENNEBERRY: Okay. The last set of slides are what we called unresolved issues. And these are things that we talked about. We just have not finished putting final language together for a recommendation. And we need to do more work on these.

We are not sure whether they will stay in the report or come out of the report or be modified. But we wanted to share them with you so that you know things that perhaps we are wrestling with a little bit and welcome any feedback or help or information that you all might have for us that could move us forward on these recommendations.

And this first one really goes to some of the

issues that we have talked about several times today. And we just weren't sure what to do about this. And I think, I don't know if it was Laurie or Anne Marie who brought up this issue.

But the recommendation we very much acknowledge the critical role that pharmacists are going to play in counseling beneficiaries. Especially around the clinical concerns of their plan.

But a couple of people did raise the concern that there could be in some cases a conflict of interest for a pharmacist to get too engaged in those conversations. So we just weren't sure as of 5:00 o'clock yesterday what to do with this and how to write something that reflected all of the issues that this raised for us.

And I think after some of the discussion today we probably are better off than we were yesterday. But that is where it sits for now. And I welcome any other comments about this. Jay, did you want to say anything more about this?

DR. CURRIE: (Nodding of head.)

CHAIRPERSON HENNEBERRY: Okay. Any reaction from the audience?

(No response.)

CHAIRPERSON HENNEBERRY: Okay. I think we covered this. And then the last one, it's sort of, it's very

interesting that this is last because you might also think, one might think that this would have been one of the very, very, very first things we ever talked about as a commission. And in some ways we did.

We just didn't talk about it as a great big decision making point. But it certainly came up woven, if you will, throughout all of our discussions. Especially the big over arching discussion about what is the best role for an individual SPAP to play in their own state for their own beneficiaries given what the market might look like.

But this is that SPAPs should have the option to act as a PDP sponsor for their SPAP members. And that is kind of as far as we got with this. Certainly on one hand we said well, yes, if they want to. And then when we started talking about what it might really take for an SPAP to legally be able to look like and call itself a PDP sponsor we pretty much thought well who is going to do that.

And then we thought well maybe there are other words. Maybe they could be treated just like PDP sponsors. Or they could act on behalf. I mean there were all sorts of verbs that we plugged in.

But the point is that we, this is consistent with our flexibility principle. And I think we do feel that if there is a state where the SPAP wants to jump through whatever hoops it has to jump through and in their particular

market they think they would be a competitive PDP sponsor, go for it. We don't want to recommend anything that would stand in the way of that. But we really didn't get much farther than that in terms of our deliberations.

So that is why it is stuck on the unresolved issues slide. I am not sure where we are going to go with this. And we welcome any reaction or response or concerns that the audience might have. Marc.

MR. RYAN: If I could maybe put a pitch in for this. I was one of the guys from states that were lobbying Congress for essentially the ability to get a monthly PMPM if you decided that you wanted to just cover your beneficiaries through your SPAP.

So almost pharmacy plus waiver in some weird way. And the argument that was used by many folks in Congress at the time was that they felt that PDPs were rather liberal in terms of formula. They were more costly than the plans that they wanted to implement through Part D, which frankly makes sense. I understand that.

But I would argue that this should be a viable option because if an SPAP decides to do that for administrative ease they clearly are at risk for anything above that basic benefit anyway. They are making that choice just as if many of us will wrap around if we don't have a choice to become an SPAP.

And the program would still be getting the benefit of very cost effectiveness with other PDPs out there driving down some of the costs through the prescription drug plan. So I think it arrives at a pretty good middle ground.

And if CMS were to recognize the fact that we are going to wrap around anyway and provide that more liberal supplemental benefit against a core more cost effective benefit from an administrative ease standpoint it's a pretty valid thing for CMS to consider.

CHAIRPERSON HENNEBERRY: Anyone else on the commission want to speak to this?

MS. SCHOFIELD: Just one quick point which Marc has raised before too, which was we have in our group considered this as a temporary fix for states that aren't yet ready to go through the whole integration process with the PDP plan.

MR. RYAN: If I could augment that. That is a great point by Linda that we talked about in our group. Frankly we are very, very worried that as late as this roll out may be, you know September for a choice of plans. November starting enrollment. January starting the program. That the PDP, the SPAPs although we are sort of on the ground floor of this. We are almost at the back end of the process to wrap around. And physically it may be impossible.

So as Linda noted this idea if not adopted permanently may be at least a short term proposition, six

months to a year perhaps, of allowing states the option to get the actuarially equivalent per member per month that CMS is estimating to ramp up and to actually wrap around the new benefit.

CHAIRPERSON HENNEBERRY: Okay. Question. Kim.

MS. FOX: Actually it's not related to that particular point, which I think is a great point. But rather that one thing that isn't in the unresolved issues and I saw notably was not mentioned throughout is the issue of rebates. And how the SPAP should weigh in related to the transparency issue.

CMS is going to be getting information from the PDP sponsors about the rebates. But they aren't required to share that with the states. And the state won't be aware of how much rebate is going to be actually included in the price.

All of those things have significant implications on the states relative to their current rebate receipts versus what they can anticipate in savings in the future. And it seems to be something that the commission should at least address and potentially recommend that CMS share that information with the states as another government agency that is using tax paying dollars.

CHAIRPERSON HENNEBERRY: Well, we were hoping you wouldn't notice that.

(Laughter.)

CHAIRPERSON HENNEBERRY: We actually did talk a lot about rebates. And again struggle is probably too strong of a word. But really did go back and forth and back and forth about what we should say and what, especially trying to meet the test of how did it directly affect SPAPs and SPAP beneficiaries.

But I am going to ask, I think there were one or, maybe all the committees. But I think one or two committees really had the lengthy conversations about rebates. And let them speak to that. Bob.

MR. POWER: I have slightly lost track of what the final, final documents say. But we have --.

CHAIRPERSON HENNEBERRY: Nothing.

MR. POWER: Nothing. Oh, goodness. Some of us drafted language that essentially recommended that states would give up their rebates essentially to the PDPs in the sense that the PDPs would then wield the total market clout combined of both the SPAPs and the PDPs own other business in achieving, receiving, and implicitly and indirectly passing the rebates on to the states by that mechanism.

MS. SCHOFIELD: We had a lot of discussion about this in my group. And quite frankly we didn't comment on it in the paper because there was not a consensus about it.

CHAIRPERSON HENNEBERRY: In the NPRM letter, you

mean.

MS. SCHOFIELD: In the NPRM letter. But we had -- or in our papers. But we had a lot of discussion. And there were very strong proponents of allowing the states to negotiate their own rebates in addition to the rebates that the PDPs would be negotiating. In essence getting double rebates from the same drugs potentially. Or asking.

Another idea was that during the donut hole that the SPAPs since they were paying could collect the rebates. And the PDPs couldn't. Although obviously administratively that is a big issue. And there were very equally strong opponents of those kinds of ideas.

And I think quite frankly that there was such a lack of consensus or even a clear majority that it was just something that we determined best not to recommend and let each stakeholder make their own recommendation. Because we weren't going to come to a majority opinion on it.

CHAIRPERSON HENNEBERRY: We do plan if necessary to have a section in our report that would address these unresolved issues. Things that we spent time on and thought about and investigated. But, we --. Or call it minority opinions even. That we could not as a commission agree on. And this may end up falling, it might not be anywhere, but it may end up in that part of the report too. Marc.

MR. RYAN: I guess I think what Kim just talked

about is at least a reasonable suggestion to include in the report at the right time. I mean I don't think there is any good answer, silver bullet here. It's probably going to be years before we really know what the effect is.

But, as a state representative I would say already you can see an erosion of power which could have a dramatic impact on other buying whether it's what Linda just pointed out about the rebate effectively accruing to the PDP or MA-PD during the donut hole when actually SPAPs will actually be paying the full cost of that to what I think are real issues between preferred and non-preferred and the cost shift to state as well as other related pharmacy network issues.

I think there clearly is an erosion on behalf of states to buy effectively. And at the very least if we can't come to a consensus the transparency issue at least gets you to a point where over time you can figure out what the net impact is.

MS. SCHOFIELD: Can I just ask Kim a clarification question? So is what you are suggesting that, I think I didn't hear you saying necessarily that states should also get rebates in addition to the PDPs.

I mean part of my concern was the more people you have trying to get rebates you erode it for every, you erode the clout that Marc is talking about for everybody. That if you want the most successful negotiation to drive prices down

you want to concentrate the bargaining power of one power.

But I think what I heard you saying was that you want that whatever negotiations occur between the payer and the manufacturer to be made public.

MS. FOX: Right. Public to the state. I mean I know you guys are dealing with major differences of opinion about whether the state should pursue its own. Actually I wasn't even raising that. Because I figured it was incredibly controversial.

MS. SCHOFIELD: And it's just --.

MS. FOX: My question is just transparency. I mean because transparency is required. In other words the PDPs are required to CMS their rebate amounts that they are getting per manufacturer. And also the percentage that they are passing on to the price.

CMS will have that information. The states will not. And I am just saying that it seems to me that as a again entity that is a government entity and trying to be able to assess its costs it would be beneficial for the states to also get that information.

MS. SCHOFIELD: So you are not suggesting that the real proprietary guts of a contractual negotiation be made available to the states. Because obviously I mean having managed care plans before you never reveal to anybody what your paying hospital A because hospital B will instantly, you

know there are big competitive issues about disclosing all of that kind of private information.

MS. FOX: I would just say whatever they have to disclose to CMS would be in the interest --. I don't know actually the specifics of what CMS is going to require in terms of transparency. But that that information should be available also to the states as the secondary payer that is also a governmental entity.

CHAIRPERSON HENNEBERRY: All right. Marty and then Jim.

MR. SCHUH: I think the follow up I had on this question would be this kind of plays into our whole notion of a preferred PDP. And that is the PDP who steps forward with full transparency to the state and wants to partner with them in saying, listen, we may give you the rebate back 100 percent. We may keep some for ourselves. But any way we will be under full disclosure. So a state may choose that route as opposed to going it alone.

MS. FOX: I agree that a preferred card you would essentially get that information because you would be working with that one card. I am talking about in the situation where you might not have preferred cards. And also with the MA-PD I suppose as well.

CHAIRPERSON HENNEBERRY: Jim.

MR. CHASE: I was just trying to clarify that too.

Because I certainly would be interested as a purchaser in having transparency in that. But I don't know how. It's my understanding that the setup is that the information is disclosed to CMS because they need that for rate setting, basically, purposes.

But if you disclose that then to all the states you have sort of blown through the privacy. I mean we might be held to a privacy standard. But once it goes out to 50 states how do you actually maintain that proprietary nature of the data?

So I certainly would be interested in it. But we would obviously have to be able to guarantee that the information would not become public.

MS. SCHOFIELD: And I think there is another issue there, to just point out. And that is that the states are not only just governments. They are also negotiating rebates themselves. And so when you are giving them the advantage of knowing what other negotiators have obtained it kind of, you know, it just affects that competitive market dynamic.

CHAIRPERSON HENNEBERRY: Marc.

MR. RYAN: I think those concerns are merited. But I think you could get to a gross level data concept to at least measure what the rebate on average is within the program against the that the states have suffered.

And I would also argue that in the end in this

public world when you begin looking at what rebates we are getting, I mean given Medicaid's best price. I mean we sort of really know what is out there. And it's pretty easy to I think in the end to figure out what the commercial discounts are equal to.

MS. SCHOFIELD: But the fees don't have to meet. The fees can be better than Medicaid best price.

MR. RYAN: I understand. But I just still think that we don't live in a perfect system. I mean if this is a public sector program and we are already aware of the general nature of discounts and Medicaid. And oh, by the way, if the discount prices are that much better than Medicaid we should be receiving some benefit from that on the state side I would hope along the way.

CHAIRPERSON HENNEBERRY: So now you know what this is on this, not on the slide.

(Laughter.)

CHAIRPERSON HENNEBERRY: Okay. Any other comments about that?

(No response.)

CHAIRPERSON HENNEBERRY: There actually is one other bullet that someone raised to me during a break that I want to mention. And that it's not so much an unresolved issue. I mean maybe it's --. I am not sure where we talked about this. But it's the notion of states that currently

don't have SPAPs creating new SPAPs in order to qualify, to be a qualifying SPAP to coordinate benefits.

And you know we didn't, I don't even remember if we made a recommendation on this. But it certainly again is consistent with our values around states having flexibility.

And there, certainly if a state has general fund money or tobacco settlement money or whatever other revenue source and they want to create a new SPAP in order to enrich the benefits in Part D we certainly would support their ability to do that.

All right. That is it. Do we have any other reaction, comments, omissions, things that you in the audience are concerned about that you did not see up here during the course of the day that you would like to bring to our attention?

(No response.)

Next Steps

by Joan F. Henneberry, Chairperson

CHAIRPERSON HENNEBERRY: What will happen now, we will take back the comments and recommendations and feedback that you all gave us today. The subcommittees will continue to meet probably for another couple of weeks to go back and look at the drafts of their papers that are going to be making up the report. And think about how to cooperate the feedback that we got from you today.

And then as I said really in early November we move into a more of a final writing and editing and making this look pretty kind of a paper. With drafts coming out probably one or two times for commission members to look at before we submit a final report for editing and printing in early December.

So I thank you all very, very much for being here today. We are going to go into a short closed session for the commission members to talk about our work plan over the next few weeks. But thank you very much for being here. We really appreciated your feedback.

(Applause.)

(Whereupon, the meeting was adjourned at 3:30 p.m.)